

EXHIBIT F

In Re Budke Jury Trial Official Transcript Vol VI 1/12/2015

1 IN THE CIRCUIT COURT
2 TWENTY-SIXTH JUDICIAL CIRCUIT
3 CAMDEN COUNTY, MISSOURI
4 DONALD BUDKE,)
5)
6 Plaintiff,)
7)
8 v.) No. 10CM-CC00085
9)
10 LAKE AREA WOMEN'S CENTER OF)
11 OBSTETRICS & GYNECOLOGY,)
12 a subsidiary of Lake)
13 Regional Medical Management)
14 Inc., f/k/a Lake of the)
15 Ozarks Medical Management,)
16 Inc.; BECKY SIMPSON, M.D.;)
17 JOHNSON & JOHNSON, a)
18 New Jersey corporation;)
19 ETHICON, INC., a New Jersey)
20 corporation; and)
21 GYNECARE WORLDWIDE,)
22 a division of Ethicon, Inc.)
23 a foreign corporation,)
24)
25 Defendants.)

14 TRANSCRIPT - JURY TRIAL
15 VOLUME VI
16 January 12, 2015

19 On January 12, 2015, the above cause came on
20 for Jury Trial before the HONORABLE WILLIAM R.
21 HASS, Judge of the Camden County Circuit Court at
22 Camdenton, Missouri, a jury of 12 and three
23 alternate jurors.

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1 (Proceedings began at 9:09 a.m.)

2 (The following proceedings were
3 held in the courtroom outside the presence of the
4 jury:)

5 THE COURT: Are you ready? Okay.
6 Would you call Tony and tell him to bring the jury
7 up?

8 THE BAILIFF: Yes. Bring them in?

9 THE COURT: Yes, we're ready.

10 (The following proceedings were
11 held in the courtroom in the presence of the
12 jury:)

13 JUROR: Good morning.

14 THE COURT: Good morning. Looks
15 like maybe there's -- are there any obstacles over
16 there? Just want to make sure you can get
17 through.

18 THE BAILIFF: All rise.

19 Camden County Circuit Court is now in
20 session, the Honorable William Hass residing.

21 THE COURT: You may now be seated.
22 I hope you had a good weekend.

23 JUROR: Yes.

24 THE COURT: And at least we
25 escaped a big ice storm so far.

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1 JUROR: So far, yes.

2 THE COURT: Knock wood. Well, I'm
3 hoping it will just be nice to us and hold off and
4 not do anything. It will make it a lot better.

5 I guess we're ready to start, Mr. Slater,
6 whenever you are.

7 MR. SLATER: Thank you, Judge. We
8 call Dr. Anne Weber.

9 THE COURT: If you'd please raise
10 your right hand to be sworn.

11 (At this time, the oath was administered to the
12 witness by the Court.)

13 THE COURT: All right. Be seated.

14 THE WITNESS: Actually, with your
15 permission, Your Honor, I'd like to stand.

16 THE COURT: All right. Well,
17 that's all right too.

18 MR. SLATER: It's for medical
19 reasons, Your Honor.

20 THE COURT: I'm sorry?

21 MR. SLATER: For medical reasons.

22 THE COURT: That's fine.

23 Should you get tired or need to sit, you
24 will have my permission to sit, but do what you
25 wish.

1 THE WITNESS: Thank you.

2 DR. ANNE WEBER,
3 called as a witness on behalf of the Plaintiff,
4 being sworn by the Court, testified:

5 DIRECT EXAMINATION

6 QUESTIONS BY MR. SLATER:

7 Q. Good morning, Dr. Weber.

8 A. Good morning.

9 Q. Dr. Weber, we're going to talk a little
10 bit about your background before we talk about
11 some of the issues in the case. Is that all
12 right?

13 A. Yes.

14 Q. Can you tell the jury where you live?

15 A. I live in Baltimore, Maryland.

16 Q. We've put up on the table just in front
17 of you your CV, your curriculum vitae. It should
18 be right -- just below you. Next level down.
19 Nope. Down below. Down there.

20 A. Oh, I'm sorry. Yes.

21 Q. So if you need to refer to that, it's
22 perfectly fine. Exhibit 2105.

23 But in any event, would you tell the jury
24 about your educational background, where you went
25 to school, and take us through that, please?

1 A. Yes.

2 I went to college at the University of
3 Maryland, and I also went to medical school at the
4 University of Maryland, and I did my residency in
5 obstetrics and gynecology at Hartford Hospital in
6 Connecticut.

7 And when I finished my residency, I
8 realized I wanted additional experience in
9 gynecologic surgery, so I attended the advanced
10 surgery fellowship at the Cleveland Clinic, which
11 is in Cleveland, and that was a one-year program.

12 And after I completed that, I then joined
13 the staff at the Cleveland Clinic as a
14 gynecologist.

15 **Q. Would you tell the jury what the**
16 **Cleveland Clinic is, please.**

17 A. Yes. So the Cleveland Clinic is a
18 tertiary referral center as well as a primary care
19 center, but the tertiary referral center is -- you
20 may know means people are referred in from the
21 community when they have problems that are
22 particularly difficult to solve or if they've
23 exhausted the resources in their community and
24 they need some additional expertise.

25 So it's a very large institution, some

1 10,000 employees.

2 Q. Can you tell the jury, when you began to
3 work at the Cleveland Clinic and joined the
4 staff --

5 And what year was that, again?

6 A. That was in 1993.

7 Q. Can you tell the jury what it was that
8 you were doing professionally at that point in
9 time?

10 A. Yes. So I began my practice in general
11 gynecology. I didn't practice obstetrics, which,
12 you know, is delivering babies. Even though I was
13 trained in that, I wanted to focus on gynecology.

14 And so that was the beginning of my
15 practice where I was seeing women of all ages,
16 well women care, problem visits, and also what
17 ultimately became my specialty -- and we'll talk
18 about that -- women with prolapse and
19 incontinence.

20 Q. And I was actually going to ask you: Can
21 you tell the jury about that?

22 As you worked at the Cleveland Clinic and
23 your career went forward, did you begin to have a
24 specialization and a focus to your medical
25 practice?

1 A. Yes.

2 So since I had the advanced training in
3 the fellowship, I had advanced surgical training
4 and I realized that I'd like to focus on that in
5 my clinical practice.

6 So that within a few years of starting my
7 practice at the Cleveland Clinic, I was able to
8 focus on women with pelvic floor disorders, which
9 is the big group of women, big category, and in
10 that group includes women with prolapse,
11 incontinence, other pelvic issues that I was
12 helping to take care of.

13 Q. And you've mentioned it, so you want to
14 just give the jury a little bit of background?

15 They've heard a little bit, but if you
16 could just give them a simple overview:
17 prolapse, what is that, what were you treating.

18 A. Okay. So prolapse is when there's some
19 relaxation or dropping down of the pelvic organs.

20 The vagina loses its support when some of
21 the muscles lose their tone and some of the
22 connective tissue gets stretched, and the other
23 organs nearby -- the bladder in the front of the
24 vagina, the uterus at the top of the vagina, the
25 rectum behind the vagina -- those depend on the

1 vagina for their support. So if the vagina loses
2 its support, then those organs drop down also.
3 And that's essentially what prolapse is.

4 **Q. In your work at the Cleveland Clinic, did**
5 **you have teaching responsibilities?**

6 A. Yes.

7 **Q. Would you tell the jury about that,**
8 **please?**

9 A. Yes. We had medical students, we had
10 residents, and we also had fellows.

11 When I went through the advanced surgery
12 fellowship, that was a one-year program, and then
13 as urogynecology --

14 That's the name for specialists in
15 prolapse and incontinence is urogynecology.

16 As that became a little more formalized
17 as a subspecialty, the fellowship in that training
18 became three years, so we had fellows who were
19 attending a program of three years in length.

20 After they did their four-year residency
21 in obstetrics and gynecology, then they did a
22 three-year fellowship in urogynecology, and I was
23 involved in training them, helping to take care of
24 patients, and also training them in research
25 methods, and assisting them in performing their

1 own research.

2 Q. Were you board certified at any point?

3 A. Yes.

4 Q. And when was that?

5 A. That was in 1995.

6 Q. And who board certified you?

7 A. That's the American Board of Obstetrics
8 and Gynecology.

9 Q. And just very simply, what does it mean
10 to be board certified?

11 A. So this involves a written test that you
12 take after your -- after you've completed your
13 residency, and then an oral examination after
14 you've been in practice for a couple of years,
15 where you collect a case list of patients, an
16 example of the kind of patients that you see in
17 your practice and how you're taking care of them,
18 and you submit all that information to the board
19 and then you have the oral examination where they
20 question you on not just your care of these
21 particular patients but all the issues that can
22 come up in obstetrics and gynecology.

23 And then once you've passed that, you're
24 board certified, you're certified by the American
25 Board of Obstetrics and Gynecology, to be an

1 obstetrician-gynecologist.

2 **Q. In looking at your CV, I saw that between**
3 **1994 and 2000, you were the director of clinical**
4 **research, department of obstetrics and gynecology,**
5 **at the Cleveland Clinic.**

6 A. Yes.

7 **Q. What does that mean, "director of**
8 **clinical research"? What was your position and**
9 **what were your responsibilities?**

10 A. So my role was to assist not only the
11 fellows and also the residents, as I've mentioned,
12 but also the other faculty member in -- faculty
13 members in the department of gynecology and
14 obstetrics at the Cleveland Clinic.

15 And what I realized, when I had such a
16 strong interest in research, that the training I
17 had had to that point really wasn't sufficient if
18 I wanted to really conduct high-quality rigorous
19 research.

20 So I attended a program at the University
21 of Michigan, in the school of public health, and
22 that was a two-year program where I earned a
23 master's in clinical research design and
24 statistical analysis.

25 And when I graduated from that program,

1 the chairman of my department created this role as
2 the director of clinical research, which hadn't
3 existed before, but since I brought this extra
4 level of training, I could then assist, as I said,
5 the other trainees and the faculty in the
6 department so they could benefit from my
7 experience and training and raise the level of
8 their research.

9 **Q. You said that you went to the University**
10 **of Michigan and obtained a master's of science in**
11 **clinical research design and statistical analysis?**

12 A. Yes.

13 **Q. What does that mean?**

14 A. Okay. So I know it's a big title.

15 So clinical research design, so how do
16 you study -- I'm sorry. How do you set up and
17 perform studies so that you can actually answer
18 the question that you set out to answer.

19 And as you probably know -- I mean,
20 research is, you set up a question, you want to
21 know something, and then you identify how you can
22 learn that answer.

23 So you pick a patient population, if this
24 is a clinical study, what kinds of questions are
25 you going to ask to get the information that you

1 need, and then you collect that information over
2 time, analyze the data, and report it that ideally
3 would answer the question that you started out
4 with.

5 And then the second part, the statistical
6 analysis, that's the data part where you have all
7 this information. How are you going to put it
8 together, learn what it really means. You have to
9 condense it down, of course, because at the end of
10 a study, you know, you'll have piles and piles of
11 information, so you need to analyze that,
12 summarize that, make some conclusions about it,
13 and then you get along to reporting it.

14 **Q. How did obtaining this master's degree in**
15 **study design and statistical analysis affect your**
16 **professional practice and the work you were doing**
17 **at the Cleveland Clinic?**

18 A. Yes. So as I mentioned, I was able to
19 bring this extra level of training and experience
20 to the residents and fellows who were performing
21 their research as part of their educational
22 program, and then the faculty in the department as
23 well, so I could help enrich their study designs
24 and performance so that could be done as well as
25 can be done.

1 And as -- we'll get to this in a minute
2 but this was also very important to me when I took
3 a position at the National Institutes of Health a
4 little later on in my career.

5 **Q. And that's actually where I was going to**
6 **go to next.**

7 **When was it that you became involved with**
8 **the National Institutes of Health?**

9 A. So that began in 1999.

10 **Q. And first, would you tell the jury: What**
11 **is the National Institutes of Health, the NIH?**

12 A. Right. So this is part of the federal
13 government that performs its own research.
14 They're based in Bethesda, Maryland, which is
15 right outside Washington. And they also fund
16 research around the country, and to a limited
17 extent around the world, but primarily supporting
18 American researchers to perform research in all
19 fields.

20 And how I became involved in this
21 position, as I mentioned, the field of
22 urogynecology was really in its infancy as -- in
23 the early parts of my career. The research that
24 had been done to that point wasn't really
25 rigorous. It wasn't the kind that allowed us to

1 draw strong conclusions about the best way to care
2 for women with these problems.

3 And the NIH recognized this as a public
4 health problem and realized that this had not been
5 a focus of their funding in the past, and so at
6 the -- members of the professional organizations
7 that I belong to proposed to NIH that they create
8 a special program for research in women with
9 pelvic floor disorders, and then in 1999 I was
10 given that job to begin that program at the NIH,
11 to attract investigators.

12 Since this hadn't been a focus before,
13 there weren't a lot of investigators submitting
14 their own proposals for research because it hadn't
15 really been recognized as a high priority, so the
16 funding wasn't readily available.

17 So what we got in the beginning -- you
18 know, the late 1990s into the early 2000s -- was
19 some dedicated funding for pelvic floor disorders
20 in order to stimulate investigators, get some
21 high-quality research done, and really help
22 advance the science as far as the best way to take
23 care of women with these problems.

24 **Q. Once you became involved with the Pelvic**
25 **Floor Disorders Network of the NIH, what were your**

1 **responsibilities? What was your position and what**
2 **was your responsibility?**

3 A. Okay. So the Pelvic Floor Disorders
4 Network came out of these initiatives that I was
5 just talking about, and what that network is is a
6 collection of institutions around the country --
7 seven institutions that were clinical and one
8 institution that was doing the data analysis, so
9 that was the data coordinating center, so eight
10 institutions altogether -- who were working
11 together to design and perform studies about women
12 with pelvic floor disorders.

13 And as you can easily imagine, it would
14 be easier when you have seven different
15 institutions collecting patients and entering them
16 into studies rather than just one institution
17 trying to do that by itself.

18 So this was a way to bring the
19 investigators together, really take advantage of
20 all that brainpower, design rigorous studies,
21 perform them, get the information, and then report
22 this high-quality research that will help take
23 care -- better care of women with these problems.

24 So I was the program director of the
25 Pelvic Floor Disorders Network, so this was while

1 I was working for NIH, and I basically supervised
2 the investigators at the clinical sites and the
3 investigators at the data coordinating center. We
4 worked together. I ran the meetings and those
5 kinds of things to keep things going, keep things
6 organized while the group was designing these
7 studies and performing them.

8 **Q. I note that you have published in what's**
9 **called the peer-reviewed literature.**

10 A. Yes.

11 **Q. What does that mean?**

12 A. Okay. So the peer-reviewed literature is
13 the standard for reporting research in the
14 scientific community, and peer review means that
15 once an author has submitted a manuscript to the
16 journal with a report of their research results,
17 then the manuscript is sent out to usually two or
18 three other people in the field so they can review
19 it, critically review it, so that they can judge
20 the merits of the research. Was the research done
21 well, was it rigorous, did it have enough
22 patients, are the results reported clearly, all
23 the kinds of things that you want to see in
24 high-quality research.

25 And then that's returned -- all those

1 reviews are returned to the editor and then to the
2 author, where the manuscript can then be improved
3 and sent back and ultimately accepted. Not a
4 hundred percent of the time, of course, because
5 sometimes it's rejected.

6 So that's -- as I mentioned at the very
7 beginning, that's considered the standard of
8 reporting research results in the scientific
9 community.

10 **Q. In looking at your CV, I note that it**
11 **looks like that you have about a hundred**
12 **publications you've published in the peer-reviewed**
13 **literature. Does that sound right?**

14 A. Yes.

15 **Q. In looking through your CV also, you were**
16 **one of the authors of a textbook, "Office**
17 **Urogynecology," published in 2004. What was that?**

18 A. Okay. So this was a textbook --

19 The publishers approached myself and my
20 coauthors. They thought -- they saw a gap in the
21 textbooks that most of them focused on surgery and
22 anatomy and atlases and things like that, and they
23 saw a gap in providing information on how to take
24 care of women in the office when they have these
25 kinds of problems.

1 Because honestly, the vast majority of
2 women can be helped in the office and only some of
3 them need to go to surgery for their problems.

4 So this was a focus on the evaluation and
5 treatment of women with pelvic floor disorders --
6 which, like we talked about, prolapse,
7 incontinence, those kinds of things -- and how to
8 best help them from an office practice.

9 **Q. In looking at your CV, I want to ask you**
10 **about certain items that are mentioned, if I**
11 **could, and there's a section in here that is**
12 **titled, if I can get to it, "Professional**
13 **Service." I want to ask you about a few things.**

14 **One of the things you were between 2003**
15 **and 2007, "Examiner, American Board of Obstetrics**
16 **and Gynecology."**

17 **What does that mean?**

18 A. Okay. So like I was describing a little
19 bit earlier, the American Board of Obstetrics and
20 Gynecology provides certification to people who
21 have passed the written test and then the oral
22 test.

23 So of course examiners are needed to
24 administer the oral tests, and that's what that
25 role was, is testing the individuals who had

1 recently completed their training and were coming
2 in as a proposed board certification, and I was
3 one of the examiners giving them this oral exam.

4 **Q. Another thing I see is you were a member**
5 **of the editorial board of "Obstetrics and**
6 **Gynecology."**

7 **What is that?**

8 A. So "Obstetrics and Gynecology" is the --
9 one of our scientific publications that is -- the
10 American College of Obstetrics and Gynecology
11 publishes all of its documents in.

12 And I'll just -- so there are these two
13 different things: The American Board and then the
14 American College.

15 So the board is the certifying
16 organization. They give the exams. The American
17 College is the professional organization. So they
18 hold annual meetings and they have research
19 presentations and they have publications about
20 different issues in women's care and guidelines
21 and so forth.

22 **Q. I note that it says on here you were a**
23 **member of the board of directors of the American**
24 **Urogynecologic Society. What does that mean?**

25 A. Okay. So that's another professional

1 organization, the American Urogynecologic Society.

2 So people who have -- who are
3 urogynecologists or have a special interest in
4 urogynecology, they hold annual meetings,
5 scientific presentations, advance the education
6 and research in the field.

7 So I served on the board of directors of
8 this organization, so that's participating in the
9 decision-making about what does the future look
10 like for this organization, how can we best serve
11 our members, that kind of thing.

12 Q. In looking through the journal, it says
13 that you were actually a peer reviewer for -- I
14 count about 10 journals, and I think you're doing
15 that currently for one of them.

16 What does it mean to be a peer reviewer?
17 I think you've touched on it, but since you were
18 doing this for so many journals, I think you
19 should just give the jury a brief explanation.

20 A. Right.

21 So remember I was just talking a few
22 minutes ago about how a journal -- an article
23 becomes peer reviewed and then published in a
24 journal.

25 So I mentioned that it gets sent out to

1 people in the field, the reviewers. So of course
2 that means they need people to do that job.

3 So I was one of the people doing that
4 job. Which means I would receive manuscripts from
5 other authors, I would critically review it,
6 identify any -- any problems that I thought there
7 were, any points of improvement to make this
8 better, and then give that feedback to the editor
9 of the journal, who then went -- those comments
10 then went back to the author.

11 Q. And it says in this CV that you had
12 trained about 21 fellows at the Cleveland Clinic
13 in the advanced pelvic surgery fellowship.

14 Does that sound about right?

15 A. I think 21 is the number overall, because
16 I started in the Cleveland Clinic and then I went
17 to Pittsburgh.

18 Q. Okay. And I see one of the people that
19 you trained at the Cleveland Clinic was Richard
20 Hill. He's one of the experts that's been named
21 on behalf of Dr. Simpson in this case. You were
22 one of the people who trained him?

23 A. Yes.

24 Q. I think you touched on it, and I'll ask
25 you to explain a little.

1 **Did there come a time when you left the**
2 **Cleveland Clinic and moved on in your career to**
3 **another institution?**

4 A. Yes.

5 So in 2000, there was an opportunity at
6 the University of Pittsburgh, Magee-Womens
7 Hospital, which is obviously in Pittsburgh,
8 Pennsylvania. And remember I mentioned the
9 fellowships, which became a three-year program.
10 And they didn't have a fellowship in urogynecology
11 at that point at that institution, and they wanted
12 to develop one, and the staff there didn't really
13 have the -- the experience or the -- the resources
14 to start a new fellowship from scratch, so at that
15 point I decided to leave the Cleveland Clinic and
16 then go to the University of Pittsburgh to
17 continue my clinical practice and I was also still
18 working at NIH at that time, but also with the
19 goal of starting a fellowship.

20 And that was successful, I'm happy to
21 say, and that's ongoing and they're continuing to
22 train fellows at the University of Pittsburgh.

23 **Q. Now, did there come a point in time --**
24 **and you don't have to give us any details, but is**
25 **there a point in time when you stopped practicing**

1 **medicine?**

2 A. Yes.

3 **Q. And when was that?**

4 A. 2006.

5 **Q. And you can generally tell the jury just**
6 **what was the reason why that was.**

7 A. Right. So I had a medical condition that
8 was just making it increasingly difficult for me
9 to participate in surgery. You know, of course
10 I'm getting a little older, like everyone else,
11 and surgery is really a very physically demanding
12 profession, and there came a point where it just
13 didn't become -- it was not possible for me to
14 really continue. And that was in 2004.

15 And then I continued to work at the
16 University of Pittsburgh with an office practice,
17 and I continued to work at NIH, but in 2006 I
18 decided that an office practice was really not
19 what I had trained for. I'd trained to be a
20 surgeon, and since that wasn't possible for me any
21 longer, I decided not to continue with my clinical
22 practice at that point.

23 I continued to work at NIH until the end
24 of 2007, and at that point I decided that my
25 health would really benefit from some time off,

1 that there -- I was doing a lot of traveling, a
2 heavy workload, and at that point I really just
3 needed to take a break.

4 **Q. When you were practicing medicine, where**
5 **were you licensed as a physician? What states?**

6 A. So I was licensed in Connecticut first,
7 since that's where I completed my residency
8 training; Ohio; and then Pennsylvania.

9 **Q. And when you stopped practicing medicine**
10 **and treating patients, did you remain licensed?**
11 **Was there any reason to do that?**

12 A. No, there's no reason to remain licensed.
13 I wasn't going to be caring for patients.
14 Unfortunately, I didn't have a prospect for that
15 in my future. So there wasn't a real reason to
16 maintain my medical license.

17 **Q. Doctor, let me hand you what we've marked**
18 **as PLT0500. Copies to counsel.**

19 **And would you briefly tell the jury what**
20 **this is and whether you're one of the authors of**
21 **this medical journal article?**

22 A. Yes.

23 **Q. The first question is: Are you an**
24 **author?**

25 A. Yes.

1 Q. Is it an article that you are familiar
2 with?

3 A. Yes.

4 Q. Is it an article that you believe to be
5 authoritative in the field of urogynecology?

6 A. Yes.

7 MR. SLATER: Assuming no
8 objection, we'll place this up on the board.

9 MS. JONES: Your Honor, may we
10 approach?

11 THE COURT: Uh-huh.

12 (Counsel approached the bench and
13 the following proceedings were held outside the
14 hearing of the jury:)

15 MS. JONES: Your Honor, I believe
16 this is the same issue that we had last week. I
17 object to him putting up -- it up on the board. I
18 think she's entitled to state her opinions but
19 she's not entitled to put up on direct examination
20 a copy of an article, even one that she wrote, and
21 just read from it.

22 MR. BALL: The rule in Missouri
23 is -- and I'm quoting from a case -- "a learned
24 treatise is inadmissible hearsay during a direct
25 examination." Simple as that.

1 They can say they have such and such an
2 opinion and there's literature to support it, and
3 they can talk -- they can say, "Here's" -- they
4 can cite to literature that supports it, but they
5 can't just read hearsay into the record.

6 MR. SLATER: My understanding,
7 Your Honor, is that the treatise itself does not
8 go into evidence. We understand that. However,
9 if the person is talking about something they
10 actually authored and states that they actually
11 wrote it, that that can be evidential because
12 she's the author.

13 And aside from that, even with articles
14 that they didn't author, they're certainly allowed
15 to show the jury portions, testify about portions,
16 so the jury can hear that.

17 MR. BALL: No. You cannot --

18 MR. OVERBY: No.

19 MR. BALL: Go ahead.

20 MR. OVERBY: We deal, of course,
21 with medical literature all the time --

22 THE COURT: I know.

23 MR. OVERBY: -- so here's the
24 situation: I think there is an exception if it's
25 one that they've written. I think they get more

1 leeway in discussing something that they've
2 specifically written.

3 THE COURT: Yes.

4 MR. SLATER: And she's the author
5 of this.

6 MR. BALL: That still doesn't --

7 MR. OVERBY: Outside of that --
8 and we may cross this, so we might as well address
9 this now.

10 THE COURT: Yeah.

11 MR. OVERBY: Outside of that, when
12 it comes into other literature, while she could
13 cite to that as being a basis for her opinions,
14 it's still inadmissible, particularly on direct.
15 It's only usable -- used for impeachment. So she
16 could -- she could say "It's a" -- "There's
17 literature that supports my opinions," she can
18 generally refer to it, but to put it up here --

19 THE COURT: Yeah.

20 MR. OVERBY: -- it's still
21 inadmissible hearsay.

22 THE COURT: Okay. I'm going to
23 make a ruling on this because we need to move on.
24 I know plaintiff's got a lot to put on and a short
25 time to do it because, like I say, I've talked

1 since day one that we're going to split the time
2 up with everybody, so I'm going to say it's not
3 going up, but you can sure talk to her about it
4 and she can explain whatever she did as an author
5 in it.

6 MR. SLATER: Okay.

7 MR. BALL: Thank you.

8 (The proceedings returned to open
9 court.)

10 Q. (By Mr. Slater) Okay. Dr. Weber, will
11 you tell the jury what this article is, please,
12 that you were one of the coauthors of?

13 A. Yes. So this --

14 Q. And if you could, you could read the
15 title to the jury.

16 A. Okay. So the title is "Anterior
17 Colporrhaphy" -- and that's a medical term for
18 anterior repair, which you'll hear a lot more
19 about -- "A Randomized Trial."

20 Remember we talked about in my training I
21 learned how to do different types of studies, so a
22 randomized trial, just to give you some
23 background, is when women are assigned by chance
24 to one group or the other. And in this case,
25 actually we had three groups. And in that way,

1 this is the only type of study design that
2 actually allows you to draw a conclusion of cause
3 and effect. Because in other study designs, like
4 where you're just watching women over time, there
5 are so many factors involved and so many things
6 that are out of your control, that you can't draw
7 that kind of a conclusion of cause and effect
8 like, "This operation was better for these women."
9 You can't do that, except in a randomized trial.

10 **Q. And what was this study?**

11 A. So this was a trial of three different
12 techniques for anterior repair, to see if one of
13 them was better than the other two.

14 **Q. Tell the jury: What is anterior repair?**
15 **Obviously it's very relevant here in this case,**
16 **please.**

17 A. Right. So that's a surgical procedure
18 that's designed to address anterior vaginal
19 prolapse.

20 And, you know, I told you a little bit
21 about prolapse earlier, so in the -- when the
22 front wall of the vagina is dropping down, that's
23 called the anterior wall. Then the bladder drops
24 down behind it. That's called anterior vaginal
25 prolapse. And that -- the anterior repair is

1 designed to address that.

2 **Q. Is another name for that a cystocele?**

3 A. Anterior prolapse can be called a
4 cystocele, yes.

5 **Q. And just to skip ahead, Joan Budke, did**
6 **she have a cystocele?**

7 A. Yes.

8 **Q. Okay.**

9 A. She had a mild cystocele.

10 **Q. Okay. And you could continue. Tell the**
11 **jury, you know, briefly what was the significance**
12 **of this article.**

13 A. Okay. So what we learned is that the
14 three techniques that we were studying actually
15 turned out to be pretty similar in terms of how
16 they corrected the anterior prolapse.

17 And the way that we were measuring
18 prolapse outcomes at this time was by measuring
19 the anatomy. So how much had the front wall of
20 the vagina and the bladder dropped down.

21 At this point, this was -- we started
22 this study in 1996 and it was published in 2001.
23 We didn't have instruments where we could ask
24 women, "How are you doing, how are you feeling, is
25 this -- has this solved your problem." And I know

1 it might seem kind of simple. You can just ask
2 women -- right? -- and they'll tell you.

3 But in the context of research, it has to
4 be very carefully designed, so that every time a
5 woman is asked this kind of a question, it's asked
6 in the same way, you gather exactly the same
7 information, and that's the only way you can put
8 it all together at the end of the study and come
9 up with your conclusion.

10 So those things weren't available at this
11 point in time. And we'll talk about how those
12 things were developed later.

13 So the -- the techniques turned about --
14 turned out to be pretty similar.

15 **Q. In terms of this study, a randomized**
16 **controlled trial of three surgical techniques to**
17 **treat an anterior prolapse, had that ever been**
18 **done before?**

19 A. No.

20 **Q. So this was the first time this was ever**
21 **done?**

22 A. Yes.

23 **Q. Okay. What I'd like to do now -- and**
24 **this is a document that's already been utilized.**
25 **It's Exhibit 750. So counsel will have it, and**

1 I'll ask if we can put it up on the board.

2 MS. JONES: Counsel, do you mind?

3 I'm sorry?

4 MR. SLATER: Exhibit 750.

5 MS. JONES: Have you got a copy
6 that I can see where --

7 MR. SLATER: I'm out of copies.
8 The RCT, February 2, 2006.

9 MS. JONES: Your Honor, just give
10 me a second.

11 THE COURT: Okay.

12 MS. JONES: We've got to find
13 this.

14 THE COURT: Sure. We'll give you
15 a minute to find it.

16 MS. JONES: I apologize, Your
17 Honor. He doesn't have a copy for me and I don't
18 have the copies that have been here --

19 THE COURT: That's all right. The
20 documents are by the bale. I understand that.
21 I've seen the boxes and boxes of them. In fact,
22 somebody told me that maybe the -- they'd
23 generated over 2 million documents or exhibits out
24 of all these cases from around. I don't know. I
25 thought about that and thought well --

1 MR. SLATER: It's up to about
2 10 million now. 10 million pages.

3 THE COURT: Is it? Okay. Well,
4 at the time I heard about it, I sat down and just
5 did some country boy math and figured if I just
6 worked 8 hours a day reading it, I could get it
7 all done in 13 1/2 years, but I'm not sure I got
8 that much time left. Now they're generating it
9 faster than I can think about it, so we'll give
10 her a minute to get it.

11 MS. JONES: I have a copy, Your
12 Honor. I'm sorry.

13 THE COURT: You do?

14 All right. You may go ahead, Mr. Slater.

15 MR. SLATER: Thank you, Your
16 Honor.

17 Q. (By Mr. Slater) Dr. Weber, is this a
18 document you've seen?

19 A. Yes.

20 Q. And it's titled "Notes from a Meeting
21 with Vincent Lucente and Dr. Miles Murphy,
22 Allentown, Pennsylvania, to Discuss Prolift
23 Randomized Control Trial, 2nd of February, 2006,"
24 and what we'll do now is bring us to the third
25 page and then I'll just ask you to tell us what

1 **we're seeing here.**

2 MS. JONES: Objection, Your Honor.

3 May we approach?

4 THE COURT: Yes.

5 (Counsel approached the bench and
6 the following proceedings were held outside the
7 hearing of the jury:)

8 MS. JONES: Your Honor, I just
9 want to bring this to Your Honor's attention that
10 we -- one of the aspects of the trial brief that
11 we put in today is that as an expert witness,
12 she's here to talk about opinions and to express
13 opinions; she's not here to talk about company
14 documents and to be a company witness, historian,
15 or to move that forward.

16 So I'm going to object to this discussion
17 as being improper testimony. At least -- I'm not
18 sure exactly where he's going but she can't just
19 put up documents and talk about them. This is
20 not -- Your Honor, this is not the appropriate
21 subject of expert testimony. Certainly it's the
22 same -- the type of thing that the jury can look
23 at the documents and read and draw conclusions
24 from.

25 MR. BALL: It's a hearsay doc- --

1 double -- it's multiple levels of hearsay because
2 it's a company document that's hearsay, and then
3 on top of it, it's a recording of them from what
4 various people said at meetings.

5 So it's double hearsay, and under the
6 Missouri rules -- that's why we sent you this
7 thing -- the only types of things that this doctor
8 can rely upon is the doctors that regularly rely
9 upon in the field. She's a medical doctor.
10 Company documents. There's no showing that some
11 kind of company document --

12 And so this is what is intended to be
13 done all day today is use Dr. Weber as a
14 mouthpiece for company document after company
15 document after company document.

16 THE COURT: No, we're not going to
17 do that.

18 MR. BALL: Thank you.

19 MR. SLATER: Well, I -- I
20 certainly think she's allowed to tell the Court
21 what documents she's relying on for her opinions,
22 but this one I'm actually relying on because
23 part --

24 THE COURT: Here's the whole
25 thing.

1 MR. SLATER: Depends on why I'm
2 using it.

3 THE COURT: Okay. I mean, I'll
4 give you that, but if it's just to criticize what
5 the company did, hey --

6 MR. SLATER: It's actually not.
7 It's to pat them on the back for mentioning her as
8 one of the people that they would think would be a
9 good person to consult with them on their
10 randomized control trial on the Prolift.

11 THE COURT: I'll let you ask that
12 or talk about it, but we're not going to play this
13 game all afternoon. Okay.

14 (The proceedings returned to open
15 court.)

16 THE COURT: You may proceed.

17 Q. (By Mr. Slater) Pull that out.

18 At the very top --

19 First of all, what -- just so the jury
20 understands, what was the subject matter of this
21 document, considering that we don't have a context
22 for when we read the top part so we'll understand
23 why you're mentioned in this Ethicon document
24 about a Prolift study?

25 A. Yes. So Ethicon was considering

1 designing and performing a randomized trial. We
2 talked about that, what that means. And this
3 meeting was drawn together to get people to talk
4 about it and see what to do.

5 Q. And it says at the top that it was
6 discussed that they were considering adding some
7 people to help structure the RCT, and they mention
8 that you would be a better dissenting voice than
9 Linda Brubaker.

10 What does that mean?

11 MS. JONES: Objection, Your Honor.

12 THE COURT: That's sustained.

13 Q. (By Mr. Slater) Does the document
14 suggest that they were thinking that --

15 MS. JONES: Objection.

16 THE COURT: Well, let's see what
17 he -- let him ask his question and then I'll rule
18 on it.

19 MS. JONES: Okay.

20 THE COURT: Here's what I don't
21 want to do. I don't want to get into what she
22 thinks their state of mind was. If it's something
23 that she can talk about abstractly that's there,
24 fine, but --

25 MR. SLATER: Well, if Dr. Weber

1 knows what it means, she can't tell the jury what
2 it means?

3 I don't think it's interpretation. It's
4 a straightforward factual statement.

5 THE COURT: Ask your question,
6 then.

7 MR. SLATER: Thank you.

8 Q. (By Mr. Slater) What does that mean?

9 MS. JONES: Objection, Your Honor.

10 THE COURT: Overruled for the
11 time.

12 MR. SLATER: Thank you.

13 A. So they were looking for additional
14 opinions in the development of this possible
15 trial, and since they knew I had this --

16 MS. JONES: Your Honor --

17 A. -- experience --

18 MS. JONES: -- I'm going to object
19 to this as being nonresponsive. I think there's a
20 very simple question that refers to exactly what's
21 up there, as opposed to what the entire document
22 refers to.

23 THE COURT: Can you limit it a
24 little bit to talk about what this is up here? It
25 mentions her one time right there, and that's --

1 we don't need to get into the whole document to
2 figure that out.

3 A. All right. They wanted to ask my help in
4 designing this possible trial.

5 MR. SLATER: Okay. Take that
6 down.

7 I'm now going to discuss PLT0011. It's
8 the ACOG bulletin that we've discussed during the
9 trial which was authored by Dr. Weber.

10 THE COURT: 00- --

11 MR. SLATER: 0011, PLT0011.

12 THE COURT: Okay. Gotcha.

13 Q. (By Mr. Slater) Dr. Weber, are you one
14 of the authors of this document?

15 A. Yes.

16 Q. And what is this document?

17 A. So this is --

18 MR. BALL: We had this ruling,
19 Your Honor.

20 MS. JONES: Your Honor, I
21 apologize. I think that this is the same ruling
22 we just had.

23 MR. SLATER: Your Honor, she's the
24 author of the document. The law says --

25 THE COURT: Yeah, but remember I

1 told you we weren't going to publish those; that
2 you could talk to her about them. If she -- if
3 she was an author of them, she knows about them.
4 I don't know as it's necessary to go beyond that.

5 MR. SLATER: It's already been
6 published to the jury. It's a factual document,
7 Your Honor, that's in evidence.

8 THE COURT: When was it published
9 to the jury?

10 MR. SLATER: In the context of the
11 testimony of --

12 THE COURT: Of a company official?

13 MR. SLATER: Yeah.

14 THE COURT: All right.

15 MR. SLATER: Yeah.

16 THE COURT: Well, I don't think
17 she needs it if she was an author of it.

18 MR. BALL: Right.

19 THE COURT: Go ahead.

20 Q. (By Mr. Slater) Okay. Dr. Weber, we're
21 talking about PLT0011, the ACOG Practice Bulletin
22 Number 79, February 2007.

23 Did you have involvement with this
24 document?

25 A. Yes.

1 Q. And what was your involvement?

2 A. I was a coauthor.

3 Q. And what does this document represent?

4 How did you become involved and what was the
5 purpose of it?

6 A. So this is a practice bulletin that was
7 published by the American College.

8 Remember I mentioned to you a little
9 earlier they publish guidelines to update
10 clinicians as to the best way of helping take care
11 of women, and since I'm an expert in this field of
12 prolapse, they asked me to coauthor this document
13 to give clinicians an update and a summary of the
14 management -- the evaluation and management of
15 women with prolapse.

16 Q. And who was it specifically within ACOG,
17 the American College of Obstetricians and
18 Gynecologists -- what group or what people within
19 there asked you to become involved?

20 A. The committee on gynecologic practice.

21 Q. What is that committee?

22 A. So that's a committee of about eight
23 people that functions within the American College.
24 One of their purposes is obviously to develop
25 guidelines like this, update previous guidelines,

1 see if there's a gap that needs to be filled, to
2 bring that information to clinicians and help them
3 stay up-to-date.

4 Q. And you authored this and then -- and
5 then after you had authored it, what was the next
6 step? Did you submit it to the committee?

7 A. Yes.

8 Q. And what did they do with this document?

9 A. They reviewed it themselves, the
10 committee members, and they also sent it to other
11 experts in the field who were not members of the
12 committee.

13 Q. And for what purpose?

14 A. For review. For critical review.

15 Q. And at the end of that process, were
16 there meetings to discuss the review and whether
17 this would be published in the ACOG journal?

18 A. Yes.

19 Q. And what was the outcome of that? What
20 was the discussion?

21 A. The decision was to -- to publish the
22 guidelines as written.

23 Q. There's a section later on in the
24 journal, in the article, and I just want to get to
25 it and ask you about something. The jury's heard

1 about it a little bit. We're going to come back
2 to this later, but just in the context of the
3 publication --

4 A. Yes.

5 Q. -- it mentions certain recommendations
6 that you made?

7 A. Yes.

8 Q. And one of them was that the procedures
9 should be considered experimental and patients
10 should consent to surgery with that understanding?

11 A. Yes. And this is referring specifically
12 to the mesh kits like Prolift.

13 Q. And was there discussion among the
14 committee before it was published about the use of
15 the word "experimental"?

16 A. Yes.

17 MS. JONES: Objection, Your Honor.
18 Hearsay.

19 MR. SLATER: This is factual
20 evidence that Dr. Weber participated in.

21 THE COURT: Overruled.

22 A. One of the reviewers noticed the word
23 "experimental" and brought this to the committee's
24 attention that this might be a matter of
25 concern --

1 MS. JONES: Your Honor, I'm going
2 to object --

3 MR. SLATER: This is discussion
4 that Dr. Weber participated in. I don't
5 understand the objection, Your Honor.

6 THE COURT: Well, come up. Let's
7 talk about it.

8 (Counsel approached the bench and
9 the following proceedings were held outside the
10 hearing of the jury:)

11 MR. SLATER: I'd just like to say
12 for the record, Your Honor, I was concerned this
13 was going to happen, that the only strategy that
14 the defense would have with Dr. Weber is to
15 obstruct her testimony. I'm -- it's a little bit
16 frustrating because --

17 THE COURT: Well, apparently a lot
18 of judges have been frustrated with her testimony.

19 MR. SLATER: She's testified in
20 one court, Your Honor, and Judge Higbee -- you can
21 call him -- in New Jersey thought she was an
22 excellent witness or thought she was --

23 MS. JONES: Whoa, whoa, whoa.

24 THE COURT: Oh, I don't want to
25 get into a --

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1 MR. SLATER: They've said that
2 she's not liked by judges. She's only testified
3 once in her life, Your Honor.

4 MR. BALL: Your Honor, here's the
5 other thing --

6 THE COURT: Whoa, whoa.

7 MR. BALL: Here's the deal:
8 Hearsay is an out-of-court statement --

9 THE COURT: Yes, it is.

10 MR. BALL: -- so just because she
11 was in the conversation doesn't make it an
12 in-court statement. It is a hearsay, okay? What
13 somebody else told her years ago is hearsay.

14 And, you know, Mr. Slater's things about
15 trying to frustrate, all we're trying to do is
16 have the rules of evidence followed, okay? He can
17 put her on and follow the rules of evidence and
18 you won't hear a peep from us, but that's not what
19 he's trying to do. He's trying to create a lot of
20 improper testimony about company intent,
21 out-of-court statements, and all this.

22 THE COURT: Well, that's a fact
23 question for the jury to decide.

24 MR. BALL: Right.

25 THE COURT: I'm trying to give you

1 some latitude. I don't -- I just don't want
2 everybody up here every minute on every question.

3 So I know what you want to do. Just take
4 those internal company documents and spend a
5 couple of days on that, but --

6 MR. SLATER: I don't want to do
7 that, Judge. You know --

8 THE COURT: Okay. Well, then give
9 me -- prove it, then.

10 MR. SLATER: I haven't done
11 anything to give you that sense at all with her.
12 I haven't even started yet.

13 Their internal company documents are
14 important to her testimony because they're a
15 foundation for a lot of her opinions because
16 they're the facts on which she relies. Certainly
17 she can tell the jury the basis for her opinions,
18 the facts she's relying on. I mean, otherwise,
19 what does she do?

20 MS. JONES: Your Honor, we're not
21 there yet. With all due respect, the objection
22 here --

23 THE COURT: Yes.

24 MS. JONES: -- is that she is --
25 this is simply a hearsay statement and that she

1 was getting ready to testify about what somebody
2 else told her.

3 THE COURT: Okay.

4 MS. JONES: And that's hearsay.

5 THE COURT: Let's just -- let's
6 stay out of hearsay.

7 MR. SLATER: I'll ask the question
8 differently and see if she understood --

9 THE COURT: Then I'll sustain that
10 objection as it is, okay?

11 MR. BALL: You'll what?

12 THE COURT: I will sustain your
13 objection.

14 MR. BALL: Thank you.

15 (The proceedings returned to open
16 court.)

17 Q. (By Mr. Slater) Dr. Weber, let me ask
18 you a factual question.

19 When this was published, was the
20 committee aware that there would be people or
21 institutions that would be concerned with the use
22 of the word "experimental"?

23 A. Yes, that had been discussed.

24 Q. And did they still go ahead and publish
25 it?

1 A. Yes.

2 Q. We'll come back to that a little bit
3 later. I'd like to ask you a couple more
4 background questions about this, though.

5 In authoring this and writing this
6 practice bulletin giving guidelines to
7 gynecologists around the United States, did you
8 perform research? Did you analyze the use of mesh
9 kits like the Prolift as part of authoring this
10 article?

11 A. Yes.

12 Q. And I'm not going to go through them all,
13 but I counted about 82 references to different
14 articles, and you did a thorough literature
15 search?

16 A. Yes.

17 Q. Did you also speak with physicians and
18 surgeons on this topic?

19 A. Yes.

20 Q. Was this article published before you
21 ever met me?

22 A. Yes.

23 Q. Dr. Weber, do you understand that any
24 opinions you offer in this case must be to a
25 reasonable degree of medical certainty?

1 A. Yes.

2 Q. Okay. So any opinions you give, you're
3 going to give them to a reasonable degree of
4 medical certainty unless you tell us otherwise?

5 A. Yes.

6 Q. Thank you. I'm just going to put this
7 aside.

8 When was it that you first began to work
9 on my behalf and with me as an expert witness with
10 regard to the Prolift and pelvis mesh?

11 A. In January of 2010.

12 Q. And during that time, have you billed for
13 your time?

14 A. Yes.

15 Q. And do you do that on an hourly basis?

16 A. Yes.

17 Q. Okay. And have you spent a great deal of
18 time?

19 A. Yes.

20 Q. And just in this case alone, can you give
21 the jury as close an estimate as you can of
22 roughly the amount of time you've spent and what
23 you've billed, so that we have some idea so that
24 we have that out there in the open so the jury
25 will know what you've done here in this case for

1 the Budke family?

2 A. Yes.

3 So about 240 hours, which is about
4 \$88,000.

5 Q. And you bill on an hourly basis for that?

6 A. Yes.

7 Q. Outside of this, you've done other work
8 and obviously you've billed for that work as well?

9 A. Yes.

10 Q. Okay. And I'll just show you -- I'm not
11 going to bring it all up there, but in the course
12 of your work, does this binder contain some of the
13 reports you've written in this litigation?

14 A. Yes, it does.

15 Q. Including the first one, which is over
16 500 pages long?

17 A. Yes.

18 Q. Let's put up the first PowerPoint, the
19 materials reviewed. Let's talk about this case
20 now.

21 And, Doctor, we've put up here a little
22 list. Can you just tell the jury what's there and
23 what that represents in terms of what you have
24 been reviewing for -- I guess we're now up to five
25 years --

1 A. Uh-huh.

2 Q. -- plus in this case?

3 Can you give the jury an idea of the
4 types of materials you've reviewed as the basis
5 for the opinions you're going to give here before
6 this jury?

7 A. Yes.

8 Q. Please do that.

9 A. So the medical literature, like we've
10 been talking about, the articles published in the
11 scientific literature.

12 The clinical and the preclinical studies
13 that Ethicon performed, including the underlying
14 data, which means the case report forms where it's
15 actually written in for each patient the data that
16 had been collected and then the studies -- the
17 reports based on those case report forms.

18 The documents internal to Ethicon and
19 Johnson & Johnson. Hundreds and thousands of
20 pages.

21 Depositions of the Ethicon employees.
22 Dozens and dozens.

23 Depositions of the Ethicon consultants,
24 editors of the New England Journal of Medicine.

25 Product labeling and marketing documents

1 from Ethicon.

2 The medical records of Mrs. Budke.

3 And then the depositions of Dr. Simpson,
4 all the treating doctors, the experts.

5 The photograph of the explanted mesh.

6 Q. And that's a general summary of what
7 you've looked at?

8 A. Yes.

9 Q. And I would like to ask you one question.
10 The opinions that you're going to offer
11 to this jury, the Ethicon and Johnson & Johnson
12 internal documents from their files, is that of
13 importance to you in being able to give the
14 opinions you're going to give to the jury?

15 A. Yes.

16 Q. Why is that?

17 A. Yes. So reviewing all of these documents
18 really gave me the back story.

19 I had an opinion. I had a grave concern
20 about these mesh kits and I expressed that in the
21 medical literature to my colleagues, and that
22 opinion I had held and still hold.

23 What I learned from all of the work I've
24 done in this case is the information that's not
25 readily available to the public. Not to

1 scientists, not even to Ethicon's preceptors who
2 are the teachers who go out in the community and
3 teach other doctors to do things like the Prolift
4 procedure.

5 Ethicon knows things that no one else
6 knows --

7 MS. JONES: Objection, Your Honor.
8 I believe we're going into --

9 THE COURT: Well, I'll sustain
10 that. Goes to state of mind.

11 MR. SLATER: It's a factual
12 statement of whether the information's available
13 to others, I think, Your Honor.

14 THE COURT: I sustained that
15 objection.

16 MR. SLATER: Okay. Understood.
17 Okay.

18 Q. (By Mr. Slater) Suffice to say that
19 those internal documents and the facts there were
20 important to you in forming your opinions?

21 A. Yes.

22 Q. Okay. You've talked a little about
23 prolapse and I'm going to try to move through
24 this. The jury's seen illustrations of what it
25 looks like. I'm not going to put those up again.

1 What I'm going to ask you is: Can you
2 tell us how researchers and physicians measure
3 prolapse? Because I think that's going to become
4 important in some of the questioning today, so
5 just tell the jury very simply: What are the
6 measurement techniques for measuring how much --
7 for example, let's talk about what Mrs. Budke had,
8 a cystocele, how that drops down.

9 A. Right. So there are two systems that are
10 in wide use, and one that's used mainly by
11 clinicians and one that's used mainly by
12 researchers.

13 Now, the one that's used by clinicians is
14 called the Baden-Walker system. It's sometimes
15 called the Halfway system. So what that does is
16 describe how much dropping down there is, and
17 since we're talking about a cystocele or the
18 anterior prolapse, you know, I'll just talk about
19 that and that's the only thing that affected
20 Mrs. Budke.

21 So a first degree or a mild cystocele is
22 where the vagina and the bladder drops down and
23 it's still within the vaginal -- within the vagina
24 itself. It doesn't come down or past the vaginal
25 opening.

1 And then second degree is when it does
2 come to the vaginal opening.

3 Third degree is when it comes past the
4 vaginal opening and then that becomes a bulge that
5 the woman can feel and sometimes can see.

6 So that's what clinicians use, typically.
7 That's what Dr. Simpson used in her medical
8 records.

9 Then there's a system that's more
10 commonly used by researchers, and this is
11 standardized, has very detailed measurements --
12 nine of them for each time you do the
13 examination -- and that's just so researchers can
14 communicate with each other, they know exactly
15 what everybody means if they say one number, and
16 they can publish their research results and they
17 can be compared across studies because everybody's
18 using the exact same thing.

19 **Q. What type of prolapse did Mrs. Budke have**
20 **in April of 2008?**

21 A. So she had an anterior prolapse, or a
22 cystocele, that had been described by Dr. Simpson
23 in the medical records as a first degree, or mild,
24 up until she went into the hospital to have the
25 Prolift procedure, at which time Dr. Simpson wrote

1 that this was a first to a second degree, so
2 somewhere between mild and moderate.

3 So it's something --

4 As I mentioned, mild is where it stays
5 totally within the vagina and typically is not
6 something the woman is aware of. Most -- or many
7 women walking around who have had babies, vaginal
8 births, have at least some degree of -- of
9 prolapse and that's not something that they're
10 typically aware of.

11 Moderate, where it comes down to the
12 vaginal opening.

13 So Mrs. Budke was somewhere in between
14 there, as Dr. Simpson described in her medical
15 records.

16 MR. SLATER: Let's go to the
17 PowerPoint on treatment options, please.

18 **Q. (By Mr. Slater) Doctor, we've put up a**
19 **short list here of treatment options, and tell us**
20 **what this represents.**

21 A. Okay. So all kinds of different ways to
22 take care of women with prolapse. And as I
23 mentioned earlier, lots of these ways can even be
24 done in the office and only a relatively small
25 number of women need to have surgery for this kind

1 of a prolapsed condition.

2 So the first option is to do nothing.

3 This is not a dangerous condition. If the woman
4 has symptoms and she's uncomfortable, then that's
5 the reason to pursue treatment. If she doesn't
6 have any symptoms, she doesn't have any discomfort
7 or whatever, there's nothing -- there's no need to
8 do anything. It's not dangerous. Nothing changes
9 rapidly.

10 In fact, in Mrs. Budke's records, this
11 mild cystocele had been documented over years in
12 the medical record where Mrs. Budke was going in
13 for her yearly checkups, not something that had
14 changed drastically. So that's a very legitimate
15 option.

16 A pessary, that's a little device. There
17 are different shapes. A ring shape that fits
18 inside the vagina like a little -- like a little
19 donut they can slip inside and hold the vagina up,
20 and in that way hold everything up. That's an
21 option for some women.

22 The suture repair, the colporrhaphy, we
23 talked a little bit about that, so that's where
24 stitches are used to bring together the layers of
25 the vagina to reduce that dropping down, and that

1 can be done -- it could have been done in
2 Mrs. Budke's case.

3 A graft can be used, in -- sort of in
4 addition to a suture repair, where some biological
5 tissue, a donor tissue or something like that, or
6 a synthetic like a mesh, could be used in addition
7 to that stitching, just to augment that repair and
8 potentially give it a little more support.

9 Or a mesh kit like the Prolift.

10 **Q. In Mrs. Budke's case, was -- those first**
11 **three options there, were they reasonable and**
12 **appropriate options for her as well?**

13 A. Yes, definitely.

14 **Q. Now, what I'd like to do is talk a little**
15 **bit about: What was the rationale for the**
16 **Prolift? What was the reason that it was**
17 **developed? What was the need that it was stated**
18 **to be meeting?**

19 A. Yes.

20 So it -- we talked about this a little
21 bit before, about when research was done focusing
22 only on the anatomy and whether the prolapse had
23 been put back to where doctors thought it
24 belonged, there was concern that the results were
25 not as good as they could be or perhaps should be.

1 So that the idea was to bring something
2 in like mesh, hopefully to add some support --
3 this was a concept transferred from hernia repair,
4 where mesh had become used commonly -- to try to
5 come up with better anatomic results, better --
6 better -- you know, putting the bladder and the
7 vagina back where they belonged. The anatomy.

8 **Q. Okay. We're going to talk in more detail**
9 **about this, but I want to just get your opinion**
10 **out there first.**

11 **Do you have an opinion as to whether**
12 **there was a need for the Prolift system as an**
13 **alternative to a suture repair?**

14 A. Yes.

15 **Q. And what is that opinion, for the jury?**

16 A. My opinion is that it was unnecessary.

17 **Q. I'm now going to hand you something we've**
18 **marked as PLT0707 and ask you about a few**
19 **different parts of it.**

20 **It's an article. Do you find this**
21 **article to be authoritative in the field?**

22 A. Yes.

23 **Q. And what I'd like to do now is just ask**
24 **you about a few portions.**

25 **First, tell the jury what the title is**

1 and when it was published.

2 A. So the title is "Incidence and Risk
3 Factors for Reoperation of Surgically Treated
4 Pelvic Organ Prolapse," and this was published in
5 2012.

6 Q. And what I'd like to do is just take you
7 to Page 39.

8 In the interest of time, there's a
9 discussion in this article?

10 A. Yes.

11 THE COURT: What page did you say?

12 MR. SLATER: Page 39, Your Honor.

13 THE COURT: Okay. Thank you.

14 Q. (By Mr. Slater) And this was a study of
15 women who had had suture repairs?

16 A. Yes.

17 Q. And the first part of the discussion
18 states, "Our study" --

19 MS. JONES: Objection, Your Honor.
20 Hearsay.

21 Q. (By Mr. Slater) Dr. Weber, is this
22 article one of the bases for your opinions in this
23 case and one of the things you're relying on?

24 A. Yes.

25 MS. JONES: May we approach, Your

1 Honor? Maybe we can clear this up.

2 THE COURT: Yes.

3 (Counsel approached the bench and
4 the following proceedings were held outside the
5 hearing of the jury:)

6 THE COURT: You got me lost here
7 now. What's the deal?

8 MS. JONES: Well, Your Honor, I
9 thought the rule was clear that he cannot -- to
10 read from an article -- she's not an author here.
11 To read from an article is hearsay.

12 If there's an issue and it's part of her
13 opinion and she wants to express an opinion with
14 respect to it, or whatever, that's appropriate,
15 but it's not appropriate for her to simply -- or
16 for counsel to simply go through and read the
17 article to her.

18 MR. SLATER: Your Honor --

19 MR. BALL: Because the article --
20 she is stating an opinion that Prolift was
21 unnecessary.

22 THE COURT: Yes.

23 MR. BALL: She can say this
24 article supports that opinion --

25 THE COURT: All right.

1 MR. BALL: -- but she can't sit
2 there and read from it.

3 THE COURT: And read from it and
4 criticize it?

5 MR. BALL: She can't do that
6 because the author of that article is not here for
7 us to cross-examine about it, so she can't stand
8 up there and read from it. These are different
9 rules.

10 MR. SLATER: My understanding is,
11 you sustained the other objection. I understand
12 the ruling. So now the ruling is all I can do is
13 identify an article; I can't let the jury know
14 what it says so that the jury will know what it is
15 the expert is relying on?

16 I've never heard of such a thing.

17 I understand your ruling on the other
18 thing, you don't want me to put it on the board --

19 THE COURT: Right.

20 MR. SLATER: -- but how do they
21 judge her opinion if they don't know what it says?

22 MR. BERGMANIS: It's to identify
23 the article and generally discuss it so that she
24 can intelligently tell the jury why she bases her
25 opinion on it.

1 MR. BALL: That's -- but she can't
2 -- he was getting ready to sit there and read from
3 it.

4 THE COURT: Right. Okay. All
5 right.

6 MR. BERGMANIS: He's going to have
7 her just testify about what it generally says.

8 THE COURT: That didn't sound that
9 way --

10 MR. BERGMANIS: I'm sorry.

11 MR. BALL: But, Your Honor --

12 THE COURT: -- but maybe that was
13 it. If he'll do that, I'm going to bark at it.
14 Okay?

15 MR. BERGMANIS: Okay. Thank you.

16 (The proceedings returned to open
17 court.)

18 THE COURT: All right. Let's go
19 back and try that tune again.

20 Q. (By Mr. Slater) Okay. Dr. Weber,
21 looking at the "Discussion" section, I'm not going
22 to read it to you.

23 A. Okay.

24 Q. Would you explain to the jury what, if
25 anything, is of significance?

1 **Without reading the article, tell the**
2 **jury why this article is significant to you in**
3 **your opinions.**

4 A. Okay. So what the authors of this
5 article found is that the need for reoperating on
6 women who had had an operation already for
7 prolapse was actually quite low.

8 And this is in contrast to some
9 literature that has been published in the past
10 which showed high rates for various reasons like
11 lumping together people with prolapse and
12 incontinence and reasons like that.

13 So looking strictly at a population of
14 women with prolapse who had had one operation, the
15 need for another operation if the prolapse came
16 back was actually quite low.

17 **Q. Does this article provide you information**
18 **that you rely on in offering an opinion as to**
19 **whether or not surgery with sutures, which was the**
20 **alternative that the Prolift was attempting to be**
21 **an alternative to, as to whether that is effective**
22 **to treat prolapse?**

23 A. Yes.

24 **Q. And what of importance is there to you**
25 **from this article?**

1 A. Yes. So the importance is that if women
2 develop recurrent prolapse in the future, only a
3 very small number of them need surgery to take
4 care of it again.

5 And remember we talked about this a
6 little bit before, that just because a woman has
7 prolapse doesn't automatically mean she needs
8 treatment. She may not have any symptoms. She
9 doesn't need treatment at all. And there are
10 various other forms of treatment before surgery.

11 And so the point is that with the
12 reoperation so low, that can be quite reassuring
13 to women that this is not a problem that they're
14 ultimately going to be forced to face. A small
15 number will, and that's too bad, but it's nowhere
16 near as high as was thought in the past.

17 **Q. Okay. What I'd like to do now is**
18 **transition to Exhibit 1593, the professional**
19 **education deck that we've already utilized during**
20 **the trial, and we're going to go in here to about**
21 **the third page, titled "Prolapse Repair,**
22 **Unacceptable Failure Rates."**

23 And Dr. Weber, is this a document you're
24 familiar with?

25 A. Yes.

1 **Q. And can you tell the jury what this page**
2 **of the professional education teaching deck, what**
3 **this is representing, what it means?**

4 A. So this is the rationale for -- behind
5 Ethicon's development of the Prolift kit, that --
6 their representation that the traditional forms of
7 prolapse repair failed too often and that the
8 Prolift kit was going to make things better for
9 women, and this is one of the articles that I was
10 just referencing.

11 These articles in the past had reported a
12 high rate of reoperation, but there are very --
13 numerous flaws with that research. One of them,
14 as I mentioned, the fact that women with prolapse
15 and incontinence were lumped together and reported
16 as a need for reoperation, as opposed to
17 separating out, "Okay, women with prolapse, this
18 is what happened to them, women with incontinence,
19 this is what happened to them."

20 So this is not really a number you can
21 rely on. Even though it says prolapse repair at
22 the top, that's not what these numbers represent.

23 **Q. The article -- the citations here are to**
24 **three articles and I'm just going to say the names**
25 **of the first authors. Olson, Marchionni, and**

1 Clark.

2 And with regard to those three articles,
3 is there testimony from Piet Hinoul, the medical
4 affairs corporate representative, on the subject
5 you just talked about?

6 A. Yes.

7 Q. And do you rely on that, in part, for
8 your opinion?

9 A. Yes.

10 Q. And what is that testimony that you're
11 relying on?

12 MS. JONES: Objection, Your Honor.

13 THE COURT: Go ahead.

14 MS. JONES: I don't believe it's
15 appropriate for Dr. Weber to talk about another
16 witness' testimony.

17 MR. SLATER: She's relying on it
18 as an expert witness, Your Honor. It's the
19 corporate representative who bound the company in
20 his deposition. It's the testimony of the
21 company.

22 MR. BALL: That doesn't give a
23 witness an opportunity -- the right to stand up
24 here and say, "This is what somebody else said,
25 this is what somebody else said." He can put on

1 that testimony when the time comes.

2 THE COURT: Well --

3 MR. SLATER: Should I put it -- I
4 mean --

5 THE COURT: Well, I'll just let
6 you ask her if she was critical of it but let's
7 not go into it and try to think what the other
8 person was thinking at the time they wrote it.

9 Q. (By Mr. Slater) In the testimony by Piet
10 Hinoul, was he questioned about these articles?

11 A. Yes.

12 Q. And these rates of recurrence?

13 A. Yes.

14 Q. And did he agree with what you said?
15 That these rates are not actually accurately
16 stated?

17 MS. JONES: Objection. It's
18 inappropriate comment on another person's
19 testimony.

20 THE COURT: Well --

21 MR. SLATER: It's the basis of her
22 opinions, Your Honor. I mean, I don't
23 understand -- I don't understand --

24 MR. BERGMANIS: It's an admission
25 of the company. It's his testimony, not his

1 opinion.

2 THE COURT: Is what you're saying
3 now in the article which she read?

4 MR. SLATER: In his deposition, he
5 agreed with me in the deposition --

6 MS. JONES: Objection, Your Honor.
7 May we approach?

8 THE COURT: Yes, let's do. Come
9 on.

10 (Counsel approached the bench and
11 the following proceedings were held outside the
12 hearing of the jury:)

13 MS. JONES: Your Honor --

14 MR. SLATER: Judge, this is --

15 THE COURT: One at a time, please.
16 Okay. Go ahead.

17 MS. JONES: Object to him
18 commenting on another witness' testimony. That's
19 what he's asking Dr. Weber to do is to relate
20 Dr. Hinoul's testimony. He can play Dr. Hinoul's
21 testimony --

22 (Court reporter interruption.)

23 THE COURT: He can't hear.

24 MS. JONES: I'm sorry. It's not
25 appropriate for him to ask Dr. Weber to comment on

1 another witness' testimony. He can ask her about
2 her opinions but she can't comment about what
3 somebody else said.

4 MR. BALL: He's trying to do his
5 closing argument through this witness.

6 (Court reporter interruption.)

7 THE COURT: He can't hear.

8 Where were we? All right. I think the
9 last thing you said was that she can state her
10 opinion but she can't go back and say what he
11 said. Is that basically what you're saying?

12 MS. JONES: Your Honor --

13 THE COURT: Wait a minute.

14 MR. SLATER: Oh, I'm sorry. I
15 thought I was up.

16 THE COURT: Go ahead.

17 MS. JONES: I think the objection
18 was she can state her opinion as to what those
19 articles say or don't say but what she can't do is
20 to relate the testimony or comment on the
21 testimony of Piet Hinoul.

22 MR. SLATER: She's relying on the
23 testimony of the corporate- -- of the -- that's in
24 the case by the corporate rep. She's relying on
25 him also saying it's inaccurate. Why can't she

1 rely on it? That's what experts do. They rely.

2 I was stopped before and you told me when the
3 expert comes in, she can do this.

4 I've never -- the rules are that an
5 expert can rely -- she tells the basis for her
6 opinion, she tells the jury what she relied on.
7 In this case the witness happens to have said yes,
8 those are misleading numbers, and she should be
9 able to say that and say, you know, "It's not just
10 my -- it's not just my word for it but the
11 corporate representative gave the admission on
12 it."

13 MR. BALL: He's going the third
14 step. She can say "my opinion," she can say "in
15 my view Dr. Hinoul's opinion supports that," but
16 she then can't say "and Dr. Hinoul said" blah,
17 blah, blah, blah.

18 THE COURT: Right.

19 MR. SLATER: She can't show her
20 knowledge?

21 MR. BERGMANIS: Corporations only
22 testify through their witnesses, through their
23 corporate reps. I mean, it's an admission by the
24 corporation.

25 MR. BALL: Okay. So it will come

1 in when it comes in. Doesn't --

2 MR. SLATER: What does that mean?

3 I can bring in stuff --

4 THE COURT: We'll be here all day.

5 Just ask her what her thoughts of it were, okay?

6 MR. SLATER: Well, I've done that
7 already but I'd also like -- they're now going to
8 cross-examine her, and she can't say, "Well, guess
9 what. Your company agrees with me"? I mean, this
10 is --

11 THE COURT: Go back and ask your
12 question again and we'll be right back up here.

13 (The proceedings returned to open
14 court.)

15 THE COURT: Okay. Now, in the
16 context of what I've said, let's start back and
17 see where we are.

18 Q. (By Mr. Slater) Okay. Dr. Weber, I'll
19 try one last time, see if I can get my batting
20 average up a little bit.

21 With regard to what you've just stated,
22 that these rates are not accurate with regard to
23 prolapse recurrence, do you have an understanding
24 as to whether or not Ethicon's corporate
25 representative agrees or disagrees with that

1 position?

2 A. Yes.

3 Q. And what is that?

4 A. He agrees with the position that these
5 are not accurate.

6 Q. Now what I'd like to do is I've handed
7 you three articles, and we'll put up Exhibit 2656.

8 MS. JONES: I'm sorry. What --

9 MR. SLATER: P2656.

10 MS. JONES: Counsel, could you
11 tell us what you're putting up, please?

12 MR. SLATER: You'll see it. It's
13 your PowerPoint slide from opening statements.
14 It's your PowerPoint from your opening.

15 Q. (By Mr. Slater) Dr. Weber, do you have
16 an understanding this is one of the PowerPoint
17 slides used by defense counsel in opening
18 statement?

19 A. Yes.

20 Q. And what I'd like to do very briefly is,
21 there are three studies there representing
22 recurrence rates in surgeries without mesh
23 frequently exceed 30%, and I'd just like to
24 quickly go through these articles and focus on the
25 third one most, but I want to just touch on the

1 first two.

2 The 1994 study authored by Miyiazki,
3 you've had a chance to look at that study?

4 A. Yes.

5 Q. And does that study study women like
6 Mrs. Budke?

7 A. No.

8 Q. What's different about it?

9 A. These women are women with severe
10 cystocele, which is not what Mrs. Budke had.

11 Q. Let's look at the second study, the
12 Paraiso study.

13 Does that study study something that's
14 similar to Mrs. Budke?

15 A. No.

16 Q. And why not?

17 A. These are women who were undergoing a
18 procedure called a sacrospinous ligament fixation,
19 which is when the top of the vagina drops down.

20 That's not what Mrs. Budke had. Like we
21 already talked about, she had an anterior
22 prolapse. She had a cystocele, a mild cystocele.
23 No other parts of -- in the vagina were affected
24 by prolapse.

25 Q. The third study, "Risk Factors for

1 **Prolapse Recurrence after Vaginal Repair," are you**
2 **familiar with that study?**

3 A. Yes.

4 **Q. Why is that?**

5 A. I was a coauthor.

6 **Q. And what does that study stand for, and**
7 **briefly what's the message from that, as you**
8 **authored it?**

9 A. Yes.

10 So the message was, again, we're -- we're
11 learning as we're publishing these things. The
12 anatomic rates appear high, but they don't
13 represent what the woman is feeling, and --

14 **Q. Let me just stop you there. When you say**
15 **"anatomic rates," what do you mean by that?**

16 A. Okay. So that means did the prolapse
17 come back in a way that bothers the woman. So
18 that looks -- if that were true of 58%, that would
19 look bad. But that's the anatomic, which means
20 just where the organs are in position. That
21 doesn't tell you whether the woman is bothered by
22 this or not.

23 And the fact that these articles were
24 being reported like this without the accompanying
25 information "is the woman bothered or not" --

1 that's really the key question -- led to the
2 development of the kind of questionnaires that we
3 were talking about before that researchers --

4 MS. JONES: Objection, Your Honor.
5 I believe this is going far beyond the question
6 that was asked here.

7 THE COURT: Well, okay. Can
8 you -- rather than having her give a narrative,
9 could you ask some questions?

10 MR. SLATER: Sure, Judge.

11 THE COURT: All right.

12 Q. (By Mr. Slater) Doctor, I'll take it one
13 step at a time with you.

14 First of all, with regard to Mrs. Budke,
15 relevant to her, what does this article stand for
16 relative to her?

17 A. Okay. So relative to Mrs. Budke, she was
18 at a very low risk of recurrence. In other words,
19 her prolapse coming back in the future. Because
20 what we found in this study is that younger women
21 and women with more severe prolapse were at higher
22 risk for recurrence.

23 So Mrs. Budke, obviously being on the
24 other end of those two things -- she was on the
25 older end of the scale and she had very mild

1 prolapse -- she was at very low risk of having
2 recurrent prolapse, having it come back and bother
3 her in the future.

4 Q. Of the 58% of women that had an anatomic
5 recurrence --

6 And that would mean Stage 2?

7 A. Yes.

8 Q. Of those women, what was the severity?
9 How was that measured?

10 A. So that was measured by the examination
11 that I mentioned previously. It's called a POP-Q,
12 which is for pelvic organ prolapse quantification,
13 so we say "POP-Q" for short.

14 And that's the system that's used by
15 researchers, like I mentioned before, that can
16 measure points exactly and researchers know what
17 they're talking about when they talk to each other
18 and when they put things in the literature.

19 So we define things by stages, and what
20 you have to remember about stages is that it's
21 somewhat arbitrary. It's just goes with the
22 territory. If you're going to make a line
23 somewhere, it has to be somewhat arbitrary.

24 So women in Stage 2, these were women
25 primarily in very early Stage 2, and typically in

1 that -- with findings like that, that's not
2 something they would be aware of or bothered by.

3 **Q. In terms of whether or not the**
4 **recurrences for the women in your study actually**
5 **caused them to actually need another operation,**
6 **what can you tell us about that?**

7 A. Right. There were no women in this
8 report that required a new operation -- another
9 operation, excuse me, for prolapse.

10 **Q. And the last thing, you had talked about**
11 **the difference between anatomic measures and**
12 **functional measures, whether the woman was**
13 **actually being affected in her day-to-day life,**
14 **and did this article have importance with regard**
15 **to that question?**

16 A. Well, it was important in that we saw
17 that the anatomic results did not correlate well,
18 didn't match up well, with the functional results.
19 So we might measure someone as if they're in
20 Stage -- well, they are in Stage 2 and technically
21 that puts her in the category of failure, but
22 she's fine. She feels she's fine, she's not
23 having any symptoms. That's just one of the
24 weaknesses of this type of examination system, the
25 POP-Q, and that's why it's so important when

1 you're looking at the results of studies to say,
2 "Okay. That's what the anatomy says. What's the
3 function? What do the women themselves say about
4 how they're feeling?"

5 Q. In terms of --

6 That was 2004 it was published. Here we
7 are about 10, 11 years later. In terms of the
8 field of urogynecology, has it moved in that
9 direction? To recognize the importance of what --
10 what you talked about in that article?

11 A. Yes. Yes. In studies that are done
12 currently, the primary outcome is based, at least
13 in part, on how the woman is feeling, and the
14 anatomic is still important but it's not the most
15 important thing and it is not the most important
16 thing to women.

17 Q. All right. What I'd like to do now is
18 I'd like to transition into talking a little about
19 the Prolift procedure. Is that okay?

20 A. Yes.

21 Q. And what I'd like to do is ask you: Did
22 you have the chance, as part of the materials you
23 reviewed, to look at the videos that were used by
24 Ethicon in training physicians on the Prolift
25 anterior procedure?

1 A. Yes.

2 Q. And was one of those videos an animation
3 that would be helpful to you in demonstrating to
4 the jury what the Prolift procedure is?

5 A. Yes.

6 MR. SLATER: And would it be okay,
7 Your Honor -- Dr. Weber has taken a few short
8 excerpts that she'd like to narrate through to
9 explain the procedure, and they're Ethicon's
10 professional education animation video and then a
11 short excerpt from a real one. They're short and
12 she would like to explain it and they come from
13 the same procedure.

14 MS. JONES: May we approach just a
15 second, Your Honor?

16 THE COURT: Oh, yeah.

17 (Counsel approached the bench and
18 the following proceedings were held outside the
19 hearing of the jury:)

20 MS. JONES: I don't know exactly
21 what he's going to show. We haven't been
22 furnished with copies of exactly what he intends
23 to show and whether they've been cut up or not cut
24 up at all, so I don't know, first of all, whether
25 I have any objection to the actual presentation of

1 it.

2 I do object, however, to Dr. Weber, who
3 has never ever done or observed a Prolift
4 operation, discussing this surgery and how it is
5 done in this case, number one.

6 And number two, I think that it's
7 generally irrelevant and a waste of the time of
8 the jury in the fact that there's no criticism or
9 concern at all in this case about how the surgery
10 was performed.

11 THE COURT: Was performed?

12 MS. JONES: No criticism of
13 Dr. Simpson.

14 THE COURT: Okay. Can you keep
15 it --

16 MR. SLATER: It's very brief but
17 there is relevance. It will be relevant to our
18 design defect claims in showing how the mesh sits
19 and how the arms sit and that they don't sit flat,
20 that they sit roped and cause tension and pressure
21 on the mesh that causes contraction which
22 Dr. Simpson testified led to the erosion into the
23 vagina of Mrs. Budke --

24 THE COURT: Well --

25 MR. SLATER: -- so it is directly

1 relevant.

2 They're short clips. They are relevant.

3 They're from their own professional education.

4 They're from the same procedure. There's a couple

5 of short ones. It's not going to take that long.

6 And I -- I would think she could be able to

7 demonstrate it so the jury should understand what

8 the procedure is.

9 MR. OVERBY: You know, we're not

10 doing any -- most of this according to how it's

11 supposed to be done. I've never seen these clips

12 before. We've got all kinds of things flying up

13 and being published to the jury that aren't in

14 evidence and --

15 THE COURT: I know it.

16 MR. OVERBY: -- so I don't know

17 what these are. I mean, given what I --

18 MR. BALL: I think we should take

19 a break and look at them because the other

20 thing --

21 THE COURT: All right. I've got

22 other -- I was going to give a break at 11:00. I

23 just don't want to shift the whole day, but let's

24 do that. Let's take a break and that will give

25 them 10 minutes --

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1 MR. BALL: Yeah. We should be
2 able to look at them before he puts them up there.

3 THE COURT: Right. Yeah. Let's
4 do that. I'll give them a break, okay?

5 (The proceedings returned to open
6 court.)

7 THE COURT: Justice requires that
8 you not make up your mind about the case until all
9 the evidence has been seen and heard. You must
10 not discuss this case among yourselves or with
11 anyone else or comment on anything you hear or
12 learn in this trial until the case is concluded
13 and you retire to the jury room for your
14 deliberations.

15 Also, you must not remain in the presence
16 of anyone who is discussing the case when the
17 court is not in session.

18 I have about -- I have about 18 minutes
19 till 11:00. I'll tell you what, if you'll be back
20 here at five till 11:00, that clock and I may have
21 a tick or two difference, but let's take about
22 a -- right at a 15-minute break so you can do
23 whatever, and then we'll try to get back at it.

24 MR. SLATER: Your Honor, you want
25 to see that now, right?

1 THE COURT: Yeah, as soon as the
2 jury is out.

3 (The following proceedings were
4 held in the courtroom outside the presence of the
5 jury:)

6 THE BAILIFF: We're clear, sir.

7 THE COURT: Okay. Now --

8 MR. BALL: The first thing we
9 would say, Your Honor, is that if we're going to
10 do things like showing video clips and showing
11 slides from opening statement stuff, we -- to
12 avoid delays, show us ahead of time. Just -- you
13 know, he --

14 MR. BERGMANIS: Why would we ever
15 do that? In Missouri, I've never done that.

16 MR. BALL: I'm not saying -- I'm
17 not saying -- last night -- well, on the video
18 clips because there's a motion in limine about it,
19 okay? And the judge --

20 (Court reporter interruption.)

21 THE COURT: Okay. But let's do
22 this: Let's get ahead of ourselves here for the
23 rest of today and tomorrow.

24 If you're going to keep showing clips --
25 snippets and clips --

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1 MR. SLATER: This is it, this is
2 it.

3 THE COURT: All right. Good deal.
4 Okay. So y'all look at it and if you got a
5 criticism, let me know.

6 MR. SLATER: And I'm not going to
7 have Dr. Weber testify. They can just see the
8 clips, we'll play them. I'm not going to have her
9 preview her testimony but they can see what they
10 are.

11 THE COURT: Okay.

12 (Video was started at 10:43 a.m.)

13 VIDEO NARRATOR: -- repair system
14 procedure --

15 MR. BALL: Are you going to play
16 the video?

17 MR. SLATER: Part of it.

18 MR. BALL: Okay. I mean, the
19 audio is what I meant to say.

20 MR. SLATER: Partially with it and
21 partially not.

22 He's going to replay it because he had
23 the volume off. The parts that we're going to
24 play the volume [sic], he's going to do it just
25 like we --

1 VIDEO NARRATOR: During the
2 anterior placement of the Gynecare Gynemesh PS in
3 the Gynecare Prolift pelvic floor repair system
4 procedure, there are two implant straps of mesh
5 that pass through the obturator foramen on each
6 side. One superficial end, one deep.

7 In its lateral-to-medial passage, the
8 cannula-equipped guide passes through the skin,
9 subcutaneous tissue, fascia lata, gracilis muscle,
10 adductor brevis muscle, adductor magnus muscle,
11 obturator externus muscle, by the edge of the
12 inferior pubic ramus, obturator membrane,
13 obturator internus muscle, and against the finger
14 in the paravaginal space.

15 When the anterior cannulas and retrieval
16 devices are in place bilaterally, the distal end
17 of each implant strap is captured in the
18 corresponding loop of the retrieval device. The
19 loop is then pulled through the cannula to exit
20 the groin.

21 (Video was stopped at 10:47 a.m.)

22 MR. SLATER: That's it, Your
23 Honor.

24 MR. BALL: So our objection, first
25 of all, would be that it's inappropriate for

1 Dr. Weber to be testifying about this because
2 she's never done a Prolift procedure ever. She's
3 never personally been there when one was done.

4 So she is -- it's inappropriate and
5 irrelevant, and she's without sufficient
6 qualifications for her to be narrating this.
7 That's number one.

8 Now --

9 MR. SLATER: Should I answer that
10 one first or --

11 MR. BALL: Well, let me get the
12 other one out there and then you can go ahead.

13 MR. SLATER: I'll never remember
14 the first one.

15 MR. BALL: Okay. And then the
16 other is, Your Honor, that the -- with respect to
17 the non-animation part, the real-life part, that
18 that would be, first of all, duplicative and
19 cumulative. They've already shown -- they're
20 already showing the animation.

21 And number two, that the -- the
22 prejudicial impact, unfair prejudice of showing an
23 actual surgical procedure outweighs any probative
24 value in a situation like here, where there is no
25 dispute about the manner in which the surgery was

1 done or that there was any problem with the
2 implantation of the mesh.

3 Anything else?

4 THE COURT: All right. Here's --

5 MR. BALL: Anything else?

6 THE COURT: Here's my thoughts on
7 it.

8 I'll grant number two. I think the
9 animation will work fine. I don't think you need
10 to go --

11 MR. SLATER: Well --

12 THE COURT: I know you don't like
13 it, but --

14 MR. SLATER: No, but I didn't get
15 a chance to argue, Your Honor. I'm not --

16 THE COURT: Okay. Go ahead.
17 Argue, but --

18 Start from the beginning and go to the
19 end and I'll keep my mouth shut. Go ahead.

20 MR. SLATER: I appreciate it. I
21 just -- I have a lot of responsibility to the
22 Budke family.

23 THE COURT: I know you do.

24 MR. SLATER: I don't want to tick
25 you off.

1 THE COURT: And they have a lot of
2 responsibility to their clients.

3 MR. SLATER: I'm not trying to do
4 that, Your Honor.

5 THE COURT: Go ahead, go ahead, go
6 ahead.

7 MR. SLATER: Number one, with
8 regard to qualifications, obviously they can
9 cross-examine her but she's well-qualified. She's
10 studied it. She's an author of articles on this
11 subject. She authored an article for a national
12 organization about these kits. So the idea that
13 she's not qualified, I think that we can dispense
14 with that based on the standards in Missouri.

15 Number two, with regard to their concern
16 about the procedure, I don't -- I don't want to
17 give all the testimony to them, but it's directly
18 relevant to our design defect claims because it's
19 going to show, for example, the roping of those
20 arms -- you see how they came out like ropes?
21 That's not what was supposed to happen. That was
22 never studied or tested. And when that happens,
23 it turns into fibrotic bridging, it turns into
24 contraction and tightness.

25 The mesh that was removed had fibrotic

1 bridging. That's a defect.

2 Number two, when you see where the mesh
3 goes, which it never was placed there for any
4 anterior colporrhaphy procedures ever done, now
5 they're putting meshes in un-impacted parts of the
6 musculature, in the obturator section of the body,
7 where people don't operate and where the women had
8 nothing wrong with them and they implant mesh, and
9 then when they got to get it out, they do all
10 sorts of damages and Mrs. Budke suffered that
11 damage and she had her body torn up and the
12 doctors had to go in and try to remove that mesh.

13 One of the major defects is the
14 difficulty in removing it.

15 That video shows the roping in real life.
16 It's a quick short clip of a few seconds. We
17 are -- we would be very severely prejudiced and be
18 having -- not be able to put our case on.

19 This is -- this is -- this is part of our
20 case and it is specific proof of what happened to
21 this woman, and we should have the right to put
22 this evidence in front of the jury, Your Honor.

23 There's nothing prejudicial about it.
24 It's a prolapse surgery case. How can they say
25 it's prejudicial to show the jury the procedure

1 that they sold? They don't want the jury to see
2 what the procedure looks like and it's only a few
3 seconds.

4 MR. BERGMANIS: And what happens
5 in real life is different than what happens in the
6 animation. That's part of the point. That's what
7 the jury has to see.

8 Just because they have an
9 in-house-produced animation doesn't mean that's
10 what really happens.

11 MR. BALL: Your Honor, our
12 position is still the same. Your job is to weigh
13 the probative value --

14 THE COURT: Absolutely.

15 MR. BALL: -- and the --

16 This case is about infection, and there
17 is no evidence --

18 MR. SLATER: It's about
19 contraction and erosion.

20 MR. BALL: There is no evidence in
21 this case that Mrs. Budke was influenced at all by
22 this that they claim that they want to show from
23 the real -- from the real surgery. There's --

24 THE COURT: Well, when we get to
25 that and that's asked, then I'll rule on that.

1 Here's what I'm going to do on this: If
2 we don't -- and, heavens, we're never going to get
3 anywhere. I'm going to -- I'm going to let you
4 show your whole animation, the whole shooting
5 match.

6 MR. SLATER: Thank you, Your
7 Honor.

8 THE COURT: I'm going to give them
9 an opportunity to voir dire her before you start
10 on this as to whether she's ever done one, been
11 present when one was done, or if she's just basing
12 this on her academic knowledge of what she
13 believes. Okay?

14 MR. SLATER: She's qualified with
15 the academic knowledge, I would assume, so --

16 THE COURT: Well, I assume she is,
17 but I don't know what she'd know --

18 MR. SLATER: So they're going to
19 cross her in the middle of the direct? Okay.

20 THE COURT: Well, it's kind of
21 like, you know --

22 MR. SLATER: I mean, I think it
23 will be duplicative --

24 THE COURT: -- I write a manual on
25 how to fly a C-47.

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1 MR. BERGMANIS: He gets to play
2 the whole thing but they get to cross her on
3 whether she's never done one.

4 THE COURT: Yeah. Well, first
5 they're going to get to voir dire her if she's
6 ever done one. So --

7 MR. SLATER: I'll stipulate she
8 never did a Prolift procedure.

9 THE COURT: Well, just ask her
10 that. You can do it.

11 MR. SLATER: I'll stipulate to it.

12 MR. BALL: She's not even --

13 Well, it would be more than that. She's
14 never done a Prolift procedure. She's never been
15 there when one was done. She's never done it on a
16 cadaver or real person.

17 MR. SLATER: Terrific.

18 MR. BALL: She's never done any
19 kind of mesh vaginal surgery.

20 MR. SLATER: Terrific.

21 THE COURT: All right. Here's
22 what we do, then: I'll call the jury back in --

23 MR. BALL: We don't want him
24 asking our questions.

25 MS. JONES: I'll ask it.

1 THE COURT: All right. All right.
2 If you'd say -- if one of y'all will say "We have
3 stipulated to the following," okay?

4 MR. BALL: No. She's going to --

5 MR. SLATER: And just to say, Your
6 Honor, that's why I put in the RCT document
7 before. She's so unqualified that their company
8 was talking about using her to help them structure
9 the most high-level study of the Prolift that can
10 be done. She's so unqualified, she wrote the
11 practice bulletin for ACOG.

12 I mean, they could cross her in due
13 course, but all they're doing is obstructing and
14 dragging my case out.

15 THE COURT: Well, I'm trying to
16 get around that if I can, so I thought if we
17 could, you know, stipulate, then they wouldn't be
18 objecting to every bit of that.

19 MR. SLATER: I'll stipulate she
20 never did it, she never saw it during her
21 practice.

22 She stopped practicing before it came on
23 the market, Your Honor.

24 THE COURT: All right. One of
25 y'all who is more familiar with this will say "We

1 have stipulated to the following," and since
2 you're on the other side, can you do that?

3 MS. JONES: I will stipulate to
4 the following --

5 THE COURT: All right. Just for
6 the record and then -- go ahead.

7 MS. JONES: Dr. Weber has never
8 seen a Prolift surgery --

9 MR. SLATER: Well, she's seen it
10 on video. That's not a true statement.

11 MS. JONES: -- observed a
12 Prolift --

13 MR. SLATER: She's watched every
14 Pro- -- it's just not true. She's watched every
15 video you guys published.

16 THE COURT: All right. Then just
17 give me something and I'll do the stipulation.

18 MR. SLATER: Just tell it like it
19 is.

20 MR. BALL: She's never seen it in
21 person, she's never been present in person on a --

22 MR. SLATER: Yep.

23 MR. BALL: -- real person, she's
24 never --

25 THE COURT: Just a minute. Never

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1 seen one in person.

2 MS. JONES: Never done one.

3 THE COURT: On a real person.

4 MS. JONES: Never observed one.

5 MR. SLATER: In person.

6 She watched all your videos.

7 THE COURT: Okay. Never seen one

8 in person on a --

9 MR. BALL: Never done one.

10 THE COURT: Never seen one in

11 person on a real person -- on a real patient.

12 I'll use that to distinguish person from who's

13 laying there.

14 MR. BALL: Yeah. Never has --

15 never has been present when one was done on a

16 cadaver.

17 THE COURT: Okay.

18 MR. BALL: Never has done --

19 MS. JONES: Never performed one.

20 MR. BALL: Yeah. Never performed

21 a Prolift surgery.

22 MR. SLATER: I mean, does that

23 cover it or --

24 MR. BALL: No. One more. At

25 least one more.

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1 THE COURT: All right. Just a
2 minute. "Performed a Prolift surgery."

3 MR. BALL: Never done any kind of
4 surgery involving mesh for prolapse.

5 MR. SLATER: What was the
6 question? What was the last one?

7 MR. BALL: Never done any kind of
8 surgery with mesh for prolapse.

9 MR. SLATER: Not true.

10 MS. JONES: Transvaginal.

11 MR. BALL: Trans -- never done any
12 kind --

13 MR. SLATER: Not true. Now
14 they're going to split hairs? I mean now they're
15 going to -- I mean, that's just not a true
16 statement.

17 THE COURT: All right.

18 MR. SLATER: She's used mesh for
19 prolapse surgery through the abdomen.

20 MR. BALL: Never done a
21 transvaginal --

22 THE COURT: Okay.

23 MR. SLATER: Your Honor, she's
24 actually placed mesh through the vagina, so that's
25 not a true statement either. The 2001 RCT --

1 (Court reporter interruption.)

2 THE COURT: Wait a minute.

3 Please.

4 MR. SLATER: It's not a true
5 statement. She has placed mesh through the
6 vagina.

7 MR. BALL: Okay. But let me --
8 let me -- I think I can state it more simply.

9 She's never done the type of surgery that
10 was done on Mrs. Budke.

11 MR. SLATER: That's too broad and
12 it's -- she has done that type of surgery. She
13 hasn't done a Prolift.

14 THE COURT: I'll just let y'all
15 fight that out with her on it.

16 MR. BERGMANIS: On cross?

17 THE COURT: I'm going to stipulate
18 on these other ones --

19 MR. BALL: Okay.

20 THE COURT: -- and then I'll give
21 you a really wide -- give you all a really wide
22 latitude to cross-examine her on what she doesn't
23 know about them. Okay?

24 MS. JONES: Thank you.

25 MR. BALL: And then one other

1 thing, Your Honor.

2 THE COURT: All right.

3 MR. BALL: When you were saying
4 they can show the animation, does that mean both
5 the animation and the real-life surgery or just
6 the animation part?

7 THE COURT: How do you -- well --

8 MR. SLATER: It's a very
9 significant piece of proof.

10 THE COURT: You need both of them?

11 MR. SLATER: Absolutely.
12 Absolutely.

13 THE COURT: All right. You got
14 it.

15 MR. SLATER: Thank you, Your
16 Honor.

17 MS. JONES: Counsel, could you get
18 your tech folks to send a copy of that to your
19 tech folks so we'll know exactly what you're
20 playing?

21 MR. SLATER: Yeah. Sure. I mean,
22 I don't know that they can do it right now. I'd
23 really like to -- I just showed it to you.

24 MR. BERGMANIS: Send it to you
25 later?

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1 MR. SLATER: Yeah, we'll --

2 MS. JONES: Well, I've been asking
3 for exhibits for a while, so if I can get it --

4 MR. BERGMANIS: But you don't get
5 them in Missouri.

6 MS. JONES: -- before the end of
7 the day, that would be fine.

8 THE COURT: Okay. Is that fair?
9 Okay. I'm going to bring the jury in.

10 MR. SLATER: Thank you, John.

11 THE COURT: Go get my smoker and
12 all my other people.

13 MR. SLATER: Your Honor, do you
14 want Dr. Weber to go back to the stand before the
15 jury comes or after? I just --

16 THE COURT: She can wait until
17 after, if she wants to. It will give her a little
18 extra time there before --

19 MR. SLATER: Okay. That's fine.

20 THE COURT: -- when the saints
21 come marching in.

22 (The following proceedings were
23 held in the courtroom in the presence of the
24 jury:)

25 THE BAILIFF: Found them all, Your

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1 Honor.

2 THE COURT: Got them all.

3 Be seated. The jury is in.

4 Before we pick up on this again with
5 Mr. Slater, you are going to be watching a -- some
6 material that will be shown on the video screen
7 here.

8 Part of it is an animation that somebody
9 drew up of what went on, and a secondary one is a
10 real surgery on a female.

11 Now, if it -- you know, if it bothers any
12 of you, let me know, or just close your eyes, turn
13 your head down. I can't keep you from doing that.
14 But that's what they want to show and I'm going to
15 let them do it.

16 However, we have a stipulation as to the
17 doctor, who may take --

18 Where did she go?

19 THE WITNESS: I'm right here.

20 THE COURT: There she is. If
21 you'd come on over and I'll remind you you're
22 still under oath.

23 THE WITNESS: Yes.

24 THE COURT: We're going to
25 stipulate that -- that Dr. Anne Weber, who is on

1 the stand now and has been testifying pretty much
2 all morning, has never seen what you're -- what
3 you're going to see, she has never seen one in
4 person. She's never been in the operating one --
5 room when one was done on a real patient. She was
6 never present to see one done on a cadaver. And
7 that she has never performed a Prolift surgery.
8 Okay? All right.

9 MR. SLATER: Thank you. And
10 proceed, Your Honor?

11 THE COURT: Yeah.

12 Q. (By Mr. Slater) Dr. Weber, before we
13 show this, do you feel comfortable as to whether
14 or not you understand the Prolift procedure well
15 enough to narrate what you're going to explain to
16 the jury here?

17 A. Yes.

18 Q. Was there anything about this procedure
19 that was so complicated that you couldn't
20 understand it?

21 A. No. I'm an experienced gynecologic
22 surgeon.

23 Q. Okay. You can stand where you think you
24 need to, point, and we'll take you through now
25 these short clips. Please do that.

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1 A. Okay. I'd like to step forward.

2 THE COURT: All right. That's
3 fine.

4 THE WITNESS: Thank you.

5 THE COURT: Yeah.

6 (The witness left the stand.)

7 A. Okay. Shall I explain what the
8 next step --

9 Q. (By Mr. Slater) Would you -- well, I'll
10 ask -- I'm sorry.

11 MS. JONES: I'm sorry. Just the
12 way Dr. Weber is facing, I can't hear Dr. Weber.

13 I apologize, Doctor, but if you could
14 either back up or we can get a --

15 THE COURT: Oh, I see. She
16 doesn't have -- she's not wired for sound.

17 MR. SLATER: I'm afraid to turn
18 one of those on, after the last --

19 THE COURT: Yeah. Well, that's
20 why I like witnesses over there (indicating), but
21 I don't -- I never tell you you can't have them,
22 but sometimes we get catastrophes in doing that.

23 MR. SLATER: I'm still shaking
24 from the last time.

25 THE WITNESS: Okay. Great. Thank

1 you.

2 MR. BALL: There's a screen right
3 there. I don't know what we're doing here.

4 THE COURT: I don't either, but --

5 MR. SLATER: Well, she's going to
6 point to things and narrate it, and this is how
7 Dr. Weber feels comfortable. I appreciate
8 Mr. Ball's concern for our presentation, but I'm
9 sure his experts will be walking around too.

10 THE COURT: Yeah. Whatever.
11 Probably so. I don't know. Or standing on their
12 heads or whatever. But I just want to get it
13 where she can see it and I'd like to get on with
14 it. Okay?

15 MR. SLATER: Great. Yeah. We
16 would like to too.

17 **Q. (By Mr. Slater) Dr. Weber, will you tell**
18 **the jury what they're about to see, please.**

19 A. Okay. Now I have to remember to lower my
20 voice so I don't blast out your ears.

21 What we're going to be looking at is an
22 animation and then a very short couple of surgical
23 clips of the anterior Prolift procedure, which is
24 what Mrs. Budke had performed.

25 All of this material is part of Ethicon's

1 professional education, so this is what they
2 produced in-house to use with doctors in training
3 them to perform the Prolift procedure. Okay?

4 So we've already talked about the
5 anterior vaginal prolapse or the cystocele.
6 That's what the anterior Prolift procedure was
7 designed to address.

8 The first thing we're going to see is an
9 image, and I just want to orient you to things so
10 it won't -- this will be clear to you as we go
11 through.

12 (Video was started at 11:02 a.m.)

13 (Video was stopped at 11:02 a.m.)

14 A. Okay. So this is a depiction of a woman
15 as if she's in the operating room. She's lying on
16 her back. Her legs would be in stirrups like a
17 pelvic exam in the office. And I just want to
18 orient you to some of the anatomy here.

19 So you can see here in the middle, this
20 (indicating) is the vaginal opening, and then
21 above that the urethra, which is the little tube
22 that drains the urine from the body.

23 Below that is the anus.

24 And this depiction also shows some of the
25 bony landmarks because that's important in

1 performing the anterior Prolift procedure, so I
2 just want to draw your attention to a couple of
3 those.

4 Here in the front (indicating), the pubic
5 symphysis, that's the bone that's at the very
6 bottom of the abdomen.

7 And then these bones coming down here
8 (indicating) as if they're part of a triangle,
9 those are the ischiopubic rami. So "ischio" just
10 means this end of the bone (indicating), "pubic"
11 means this end of the bone (indicating), and
12 "rami" is just the medical term for the bone
13 connecting those two spots. Okay?

14 So now we're going to show just the
15 beginning part of the animation and then I want to
16 show the Prolift mesh implant when that comes up.

17 (Video was started at 11:03 a.m.)

18 VIDEO NARRATOR: During the
19 anterior placement of the Gynecare Gynemesh PS in
20 the Gynecare Prolift pelvic floor repair system
21 procedure --

22 (Video was stopped at 11:03 a.m.)

23 A. Okay. So this (indicating) is the
24 anterior Prolift mesh implant. It has this large
25 central body of mesh, and then these long mesh

1 arms, four mesh arms, that are the arms that come
2 out to the groin.

3 And we'll see -- in a little bit the
4 animation is going to tell us all the layers of
5 tissue that those mesh arms go through as part of
6 the procedure in the permanent mesh implantation.
7 Okay.

8 (Video was started at 11:04 a.m.)

9 VIDEO NARRATOR: There are two
10 implant straps of mesh that pass through the
11 obturator foramen on each side. One superficial
12 end, one deep.

13 After the anterior vaginal dissection has
14 been performed in the true vesicovaginal space --

15 (Video was stopped at 11:04 a.m.)

16 A. Okay. Now I want to orient you again,
17 just to make sure this is all clear.

18 So obviously the pelvis has just been
19 rotated, so now this is as if the woman is
20 standing up. Okay?

21 You've got the pubic bone in front, the
22 tailbone back here (indicating), and then the
23 rectum leading to the anal sphincter and the anus.
24 The bladder in the front and the urethra. And
25 then the vagina in the middle.

1 And what the narrator was just describing
2 is this incision that's made in the front wall of
3 the vagina and then the dissection that goes out
4 to each side. And "dissection" is a surgical term
5 that means basically creating a space where a
6 space didn't exist before the surgery.

7 And in that space between the rectum --
8 I'm -- forgive me, the bladder and the vagina is
9 where the Prolift mesh is going to be implanted.
10 Okay?

11 (Video was started at 11:05 a.m.)

12 VIDEO NARRATOR: In its
13 lateral-to-medial passage, the cannula-equipped
14 guide passes through the skin, subcutaneous
15 tissue, fascia lata, gracilis muscle, adductor
16 brevis muscle, adductor magnus muscle, obturator
17 externus muscle, by the edge of the inferior pubic
18 ramus, obturator membrane, obturator internus
19 muscle, and against the finger in the paravaginal
20 space.

21 (Video was stopped at 11:06 a.m.)

22 A. Okay. So the important part here is that
23 this is -- this is two of the mesh arms, one on
24 each side. The one that goes deeper travels
25 through all the same things except for one muscle

1 that just isn't in that position.

2 But what I want to draw your attention to
3 the fact is, a couple of things.

4 One, the involvement of the hip and the
5 groin would never come up in a traditional suture
6 repair where only the prolapse is addressed.

7 In the development of the Prolift
8 procedure, a whole new category of complications
9 has been added of areas of the body that were
10 never involved in the prolapse in the first place
11 and now have permanent mesh implantation --

12 MS. JONES: Your Honor, I'm sorry.
13 I'm sorry to interrupt --

14 THE COURT: Okay.

15 MS. JONES: -- but if we're not
16 just going to discuss the procedure, then I'm
17 going to ask that we proceed in a
18 question-and-answer form rather than a narrative
19 form.

20 THE COURT: Okay.

21 MS. JONES: I think that --

22 Q. (By Mr. Slater) Dr. Weber, why is that
23 significant that the mesh is being placed through
24 that portion of the pelvis where the obturator and
25 the other muscles are located?

1 **Why is that significant to you in forming**
2 **your opinions?**

3 A. So the importance is that these are areas
4 of the body that have nothing to do with the
5 prolapse, yet with the Prolift procedure and the
6 permanent Prolift mesh implantation, these areas
7 are now involved and any complication related to
8 the mesh that occurs is going to extend into those
9 previously healthy areas.

10 **Q. Okay. Are we ready to proceed with the**
11 **next piece?**

12 A. Yes.

13 (Video was started at 11:07 a.m.)

14 VIDEO NARRATOR: When the anterior
15 cannulas and retrieval devices are in place
16 bilaterally, the distal end of each implant strap
17 is captured in the corresponding loop of the
18 retrieval device. The loop is then pulled through
19 the cannula to exit the groin.

20 (Video was stopped at 11:08 a.m.)

21 A. Okay. So I want to draw your attention
22 to a couple of things before we get to the very
23 end of this video.

24 **Q. (By Mr. Slater) And I'll ask you a**
25 **question.**

1 A. Oh, excuse me.

2 Q. What is the significance about this stage
3 of the procedure and that image there? What is
4 that telling us that's significant to you?

5 A. Okay. So this is when all four cannulas
6 have been put in place, and those are the tubes
7 through which the mesh arms are going to be pulled
8 in order to get the Prolift mesh implant in the
9 space between the vagina and the bladder.

10 I want to draw your attention to a couple
11 of things.

12 One, you'll notice in the animation how
13 the body of the Prolift mesh, that -- that large
14 central portion, goes into the vagina very
15 smoothly like it's just gliding in. And we'll see
16 that's different in the real surgical video in
17 just a few minutes.

18 The other thing that I want to draw your
19 attention to is the mesh arms, and as they're
20 pulled through the cannula, they're going to
21 appear as if they retain their shape and are still
22 2 centimeters wide and flat. And again, as we're
23 going to see in the surgical video, that's not how
24 it turns out either.

25 (Video was started at 11:09 a.m.)

1 (Video was stopped at 11:10 a.m.)

2 Q. (By Mr. Slater) And what is there of
3 significance in what we've just viewed, Dr. Weber?

4 A. So this is as if the procedure has been
5 completed, and I just want to draw your attention
6 to this very large mesh burden that stretches all
7 across the pelvis.

8 Q. Why is that significant, a large mesh
9 burden?

10 A. So this is completely different than what
11 would -- a woman would experience if she had had
12 an anterior repair, which is done with absorbable
13 sutures so there's nothing permanently left in
14 place, and really by the time you put the stitches
15 in place and tie the knots, she'd probably have
16 maybe this much (indicating) suture material
17 absorbable that will go away in a few months.

18 And instead, with the Prolift procedure,
19 she has this very large mesh burden taking up the
20 entire front part of her pelvis.

21 Q. And while we have it on the screen, you
22 talked about the mesh burden. Do you have an
23 opinion as to whether or not that is a safe or an
24 unsafe thing to put into a woman's body in that
25 form?

1 A. It's un- --

2 MS. JONES: Objection, Your Honor.

3 Lack of appropriate foundation.

4 THE COURT: Well, can you put some
5 foundation to it?

6 Q. (By Mr. Slater) Dr. Weber, with regard
7 to the amount of mesh placed in that portion of
8 the woman's pelvis, have you reviewed scientific
9 literature with regard to that subject?

10 A. Yes.

11 Q. Have you reviewed internal Ethicon
12 documents with regard to what their medical
13 affairs and scientist employees thought about
14 that?

15 A. Yes.

16 Q. Have you studied the literature and those
17 documents in order to form opinions as to whether
18 or not, to a reasonable degree of medical
19 certainty, that is a safe or unsafe thing to do in
20 a woman's body?

21 A. Yes.

22 MS. JONES: Objection.

23 THE COURT: Go ahead.

24 Q. (By Mr. Slater) Please offer that
25 opinion.

1 A. My opinion is that this amount of mesh
2 left permanently implanted in a woman and at risk
3 for complications for the rest of her life is
4 unsafe.

5 **Q. Why?**

6 A. It's unsafe because it stimulates a
7 chronic foreign body reaction, inflammation that's
8 ongoing and that never settles down and goes away
9 completely, that leads to other consequences or is
10 related to where the mesh contracts and bunches up
11 on itself, where it erodes through the vaginal
12 wall. These are things that happened to
13 Mrs. Budke. Where surgery is needed, an infection
14 occurs, the mesh is infected, it has to be removed
15 because the infection can't be cleared when
16 there's a foreign body in place, typically. The
17 mesh has to be removed.

18 She went through operations to try to
19 remove mesh. The mesh -- all the mesh was never
20 removed. She suffered morbidity, not just from
21 the mesh itself but from the attempts to treat the
22 mesh complications.

23 **Q. And specifically, what happened to her**
24 **that's relevant to your opinion as to the --**
25 **whether or not this is safe or unsafe? What**

1 **happened to Mrs. Budke to illustrate that opinion?**

2 A. Mrs. Budke experienced mesh contraction,
3 which is where the mesh bunches up on itself; mesh
4 erosion, where it wears through the vaginal wall;
5 infection, where the bacteria in the vagina got
6 onto the mesh and formed this very large pelvic
7 abscess that made her critically ill.

8 This mass was so large it blocked off her
9 ureters, which are the tubes that lead from the
10 kidneys to the bladder. And they were blocked off
11 because they come into the bladder right next to
12 the vagina, and because of where the Prolift mesh
13 is placed, like I told you, right between the
14 vagina and the bladder, that's right where the
15 ureters come in, so a problem in that space is
16 going to affect the ureters.

17 She had acute kidney failure. Her
18 kidneys shut down because the ureters were blocked
19 because of this abscess.

20 **Q. And with regard to the -- the ability or**
21 **inability to remove this mesh that's in this**
22 **location in this amount, is there something about**
23 **Mrs. Budke's situation that's also illustrative of**
24 **your opinion?**

25 A. Yes. It's -- it's difficult, if not

1 impossible, to remove all the mesh, and as I just
2 mentioned, the mesh was never -- all the mesh was
3 never removed from Mrs. Budke.

4 And you saw all the layers of the muscles
5 and the -- and the connective tissue and
6 everything that the mesh has to go through, and
7 remember the design intent was for the mesh to
8 become incorporated into the tissue so it's bound
9 up in the tissue. That's what was intended.
10 Which makes it difficult, if not impossible, to
11 remove. That's a design defect. That's unsafe
12 from the get-go.

13 MS. JONES: Objection, Your Honor.
14 It --

15 THE COURT: Sustained.

16 MR. SLATER: Your Honor, it's her
17 opinion as the expert.

18 **Q. (By Mr. Slater) Do you have an opinion,**
19 **to a reasonable degree of medical certainty, as to**
20 **those -- as to whether those aspects of the**
21 **Prolift system are a safe or an unsafe design?**

22 A. Yes, I have an opinion.

23 **Q. And what is that opinion?**

24 A. My opinion --

25 MS. JONES: Objection, Your Honor.

1 Lack of qualifications and foundation.

2 THE COURT: What she bases it on
3 and the like, can you give it a little bit more
4 and then --

5 Q. (By Mr. Slater) Dr. Weber, you said
6 you've read dozens of depositions of Ethicon
7 witnesses?

8 A. Yes.

9 Q. You've read hundreds of thousands of
10 pages of internal Ethicon documents?

11 A. Yes.

12 Q. You've read all of the medical literature
13 with regard to the Prolift and similar systems?

14 A. Yes.

15 Q. Based on all of that information and your
16 knowledge --

17 Let me ask you this: Have you reviewed
18 the medical records of many women --

19 MS. JONES: Objection, Your Honor.

20 THE COURT: Sustained. You can
21 ask about her. About the -- your client.

22 Q. (By Mr. Slater) You've reviewed
23 Mrs. Budke's records? Her medical records?

24 A. Yes, I have.

25 Q. And taking that all together and

1 understanding what goes on with this device, do
2 you have an opinion that you can hold to a
3 reasonable degree of medical certainty as to
4 whether or not this is a defectively designed
5 medical device system?

6 A. Yes, I do.

7 MS. JONES: Objection, Your Honor.
8 Lack of qualification.

9 THE COURT: Overruled.

10 Go ahead and ask.

11 **Q. (By Mr. Slater) What is your opinion?**

12 A. My opinion is that the Prolift was so
13 defectively designed and so unsafe, it never
14 should have been on the market.

15 **Q. Okay. Now, there's more here to show,**
16 **right?**

17 A. Yes. What I --

18 **Q. Please continue.**

19 A. What I'd like to do is show you the
20 difference between the animation and the real
21 world.

22 And the two things that we talked about
23 I'd like to -- you to focus your attention on is
24 the placement of the Prolift mesh, where we saw in
25 the animation it's gliding in smoothly. The

1 intent is to lay flat. If it doesn't lay flat,
2 it's not safe.

3 And the mesh arms, they're supposed to
4 come out the cannulas flat, because --

5 MS. JONES: Your Honor --

6 A. -- if they don't stay flat, it's unsafe.

7 MS. JONES: I'm sorry, Your
8 Honor --

9 THE COURT: Yeah. That's all
10 right.

11 MS. JONES: -- but I -- we've just
12 got a talk going on up here, and I would much
13 rather --

14 THE COURT: I agree. I mean,
15 we're not having a medical school lecture. She's
16 an expert witness. You ask her questions, she'll
17 give you responses.

18 MR. SLATER: I'll do so, Your
19 Honor.

20 THE COURT: All right. Because
21 we're not trying to teach a class on this. We're
22 just trying to inform the jury about what she
23 thinks happened. Okay.

24 MR. SLATER: Understood.

25 Q. (By Mr. Slater) Dr. Weber, with regard

1 to what you're now going to show with regard to
2 the mesh arms, is this of significance to you in
3 forming your opinions in this case?

4 A. Yes.

5 Q. And what is of significance specifically
6 about what we're going to see that is significant
7 to you in your opinions about whether or not this
8 is a defectively designed medical device system?

9 A. What's significant to me is that in the
10 design of the Prolift procedure, built in,
11 unavoidable, is the issue of mesh roping when the
12 cannulas are removed. And we're going to see
13 that. They don't stay flat and wide.

14 Q. And why does that matter?

15 A. That matters because when they're roped,
16 that leads to an increased inflammatory reaction,
17 fibrotic bridging where the scar tissue joins up
18 with itself and makes a hard, rock hard, scar
19 tissue layer, which is unsafe, and again makes it
20 extremely difficult, if not impossible, to remove.

21 Q. Would it be helpful to now show these
22 videos?

23 A. Yes.

24 Q. Okay. Let's go ahead.

25 (Video was started at 11:18 a.m.)

1 A. Okay. So what I'd like to do is just
2 orient you here again so we all know what we're
3 looking at.

4 Similar to some of the pictures we saw in
5 the animation -- okay? -- the woman is lying on
6 her back. She's in the operating room. Her legs
7 are in the stirrups. All this blue clothing,
8 cloth (indicating) around her, are the surgical
9 drapes. Okay?

10 Here in the center (indicating) is the
11 vaginal opening. That's where the surgeons are
12 working.

13 Here, this yellow tube (indicating) is a
14 Foley catheter, so that's placed in the bladder to
15 drain the bladder during surgery so it stays
16 empty.

17 And then the cannulas, the four cannulas
18 that we saw -- okay? -- have already been placed,
19 and then these purple strings, this is the
20 retrieval device, which is what loops around the
21 end of the mesh arm and then gets brought through
22 the cannulas that drags the Prolift mesh into
23 place. Okay?

24 So what I'd like to make your -- call
25 your attention to is the contrast between this and

1 what we saw in the animation as if it went in so
2 smoothly.

3 (Video was stopped at 11:19 a.m.)

4 **Q. (By Mr. Slater) Why does that matter to**
5 **you in forming your opinions?**

6 A. The importance is, the intent was for the
7 mesh to lay flat. If it doesn't lay flat, it's
8 unsafe because it goes through all those things we
9 just talked about with the mesh roping: the
10 increased inflammatory reaction, the fibrotic
11 bridging, the scar tissue that binds up with the
12 mesh and becomes impossible -- difficult, if not
13 impossible, to remove.

14 **Q. And in giving this testimony about what**
15 **happens with the mesh, are you relying on actual**
16 **documents from inside Ethicon where they document**
17 **what you've just told the jury?**

18 A. Absolutely.

19 **Q. So they knew this?**

20 A. They knew this.

21 **Q. Let's proceed.**

22 (Video was started at 11:20 a.m.)

23 A. So right now the surgeons are just tying
24 some stitches to the mesh implant itself.

25 (Video was stopped at 11:20 a.m.)

1 A. That's how the Prolift mesh implant gets
2 into the vagina.

3 Q. (By Mr. Slater) And why is --

4 A. It's not --

5 Q. -- that significant?

6 A. It's not lying flat.

7 Q. Sorry. Why is that significant that it's
8 put in in that bunched way? What does -- what
9 impact does that have on the mesh?

10 A. Because it's bunched.

11 The next thing the surgeon is going to do
12 is close the vaginal incision. The mesh is no
13 longer visible to him or her. He can't tell --
14 she -- he or she can't tell whether the mesh is
15 bunched. It's underneath the vaginal skin. So
16 what goes in bunched stays in bunched.

17 Q. Let's continue.

18 (Video was started at 11:21 a.m.)

19 (Video was stopped at 11:21 a.m.)

20 A. So this is the end of the operation where
21 he's pulling the cannulas off the mesh arms.

22 Q. (By Mr. Slater) And what is significant
23 to you there that's on that image with those arms?

24 A. Those arms aren't flat.

25 Q. And why does that matter?

1 A. That matters because this --

2 MS. JONES: Objection, Your Honor.

3 THE COURT: Just a minute. Go
4 ahead. What?

5 MS. JONES: We've been through
6 this three or four times now, Your Honor.

7 Q. (By Mr. Slater) Let me ask a specific
8 question.

9 What impact does the roping of the mesh
10 have on the pores and the pore sizes?

11 A. Right. The roping means that the pores
12 have collapsed, right?

13 If you take any kind of a net and you
14 pull on it -- right? -- the pores collapse. The
15 openings in the net go away.

16 And that's exactly what happens when
17 these mesh arms are dragged through the cannulas
18 and they have this roped -- rope appearance. You
19 can't say it any other way. They're not flat.
20 They're roped. That means that the -- the pores
21 inside that mesh arm have all collapsed. They've
22 all been dragged flat by coming through the
23 cannula in a space that's not big enough where the
24 mesh arm can't actually lay flat.

25 And so between the pore collapse, the

1 roping, the inflammation, the foreign body
2 reaction, the mesh contraction, the mesh erosion,
3 infection, all these things happened to
4 Mrs. Budke.

5 Q. Why does the roping and the concentration
6 of the mesh, as you said, increase the
7 inflammatory reaction?

8 A. Right.

9 So it's just more concentrated. In a
10 small space, the mesh is more concentrated. It's
11 rolled up on itself.

12 In addition to the pore collapse that we
13 were just talking about, it's just the body trying
14 to fight off this foreign material, creating this
15 inflammatory reaction. The cells produce things
16 that damage other cells. That's what they do when
17 they're trying to fight something off. So you
18 have this cascade of cell damage and cell death,
19 tissue damage --

20 MS. JONES: Objection, Your Honor.

21 MR. BALL: May we approach the
22 bench, Your Honor?

23 THE COURT: Sure.

24 (Counsel approached the bench and
25 the following proceedings were held outside the

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1 hearing of the jury:)

2 MR. BALL: I've got a few things
3 here.

4 First of all, he asked her a simple
5 question --

6 THE COURT: Yes.

7 MR. BALL: -- and then she goes on
8 for three or four minutes.

9 THE COURT: Yes.

10 MR. BALL: She should be
11 instructed to keep her answers to the question and
12 brief. That's number one.

13 Number two, that he -- she has now
14 repeated things like five times. She's given an
15 opinion about what she finds defective, and why,
16 and she's repeating everything five times.

17 The third thing is that he violated a
18 motion in limine by injecting the issue of other
19 claims in this case when he asked her if she had
20 seen records of other people and -- well, I don't
21 want to say it --

22 THE COURT: What, now?

23 MR. SLATER: I'm just having
24 trouble hearing.

25 THE COURT: All right.

1 MR. SLATER: I'll try to lean in
2 more.

3 THE COURT: All right. Now number
4 one, I want to keep it this way. You ask her a
5 question, I want her to answer that and not range
6 out onto everything else. Okay?

7 MR. SLATER: Yeah. I will -- I
8 will today, Your Honor, and I'm very conscious of
9 that, but some of these questions involve multiple
10 parts to the answer. I mean, she's --

11 THE COURT: Well, like I say, I
12 want the jury -- I want the jury to get the whole
13 bale, but you're not teaching a group of residents
14 on what we're doing here, so --

15 MR. BALL: We -- we ask that the
16 witness be instructed to keep the answers short
17 and to the point, and we ask the lawyer and the
18 witness not to repeat things over and over, and we
19 ask that there be no more references that in any
20 way refer to the possibility of other lawsuits
21 which --

22 THE COURT: Yeah. Now, that --
23 that --

24 MR. BALL: -- Mr. Slater did.
25 And then I'd also ask that the -- he also

1 said "and they knew it." That is a state of mind.

2 That's another violation --

3 MR. SLATER: Your Honor, it's

4 not --

5 MR. BALL: -- of a motion. That's

6 a motion in limine violation.

7 MR. SLATER: That, I'll address.

8 It's not a state of mind in terms of

9 intent. It's a state of fact that they had that

10 information, and it's documented in the records,

11 and that goes to our failure to warn claim, our

12 negligence claim, and our defect claim, that they

13 had --

14 If they didn't have this information and

15 they learned it later, they'd be telling the jury

16 "We didn't know that. We couldn't have known

17 that."

18 That's a big part of this case to be

19 able --

20 THE COURT: Well, I've given you

21 pretty good latitude on that --

22 MR. SLATER: I appreciate that. I

23 was just responding to --

24 THE COURT: -- but I'm just saying

25 we don't need to reiterate and reiterate and

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1 reiterate that and she does not need to go on and
2 on and on.

3 If you ask her a specific question, tell
4 her to give you the answer to that, okay?

5 MR. SLATER: I'll try to do it.

6 THE COURT: All right. Try.

7 MS. JONES: And, Your Honor, I
8 think if Dr. Weber is finished with going through
9 the video, I'd ask that she retake the stand,
10 because --

11 THE COURT: Yeah.

12 MR. SLATER: I think there's one
13 more --

14 THE COURT: Well, let's do it and
15 then get it off of there.

16 (The proceedings returned to open
17 court.)

18 MR. SLATER: Actually, you know
19 what? We're fine. We can skip the last one. You
20 can go back up here, Dr. Weber.

21 THE WITNESS: All right.

22 (The witness resumed the stand.)

23 MR. SLATER: Proceed, Your Honor?

24 THE COURT: You may.

25 MR. SLATER: Thank you. Turn that

1 thing off.

2 Q. (By Mr. Slater) Dr. Weber, you just
3 explained what you explained to us with the arms
4 and the cannulas and I'm not going to ask you to
5 go through that again.

6 A. All right.

7 Q. My question is this: Did Ethicon ever
8 study whether there was a safety risk with regard
9 to the mesh being pulled through the cannulas as
10 you described it?

11 Simple yes-or-no question.

12 A. No.

13 Q. Okay. Do you have an opinion as to
14 whether or not it was appropriate or inappropriate
15 for Ethicon to sell this device for surgeons to
16 use it without studying that specific issue?

17 MS. JONES: Objection, Your Honor.

18 THE COURT: Sustained.

19 MR. SLATER: I'm not sure --

20 THE COURT: Well, she's already
21 told what she thinks about it.

22 MR. SLATER: I'm just talking
23 about failure to -- not studying the issue. It
24 was a different question, I thought. I think it's
25 part of our case.

1 THE COURT: Well, I don't know
2 whether they studied it or not. You know, I don't
3 know what they thought or said, and that's asking
4 her to --

5 MR. SLATER: I'll rely on
6 Mr. Ciarrocca's testimony where he said they
7 didn't --

8 THE COURT: Fine. All right.

9 MR. SLATER: -- but I just wanted
10 to ask her an expert opinion on that if I could.
11 I thought I was supposed to do that.

12 MR. BALL: She's not been
13 identified on the standard of care of a company
14 and she's not qualified to talk about the standard
15 of care of a company.

16 MR. SLATER: Huh?

17 THE COURT: I don't know. I don't
18 know what you're -- I'm going to let you ask the
19 one question and let's go on. Okay?

20 MR. SLATER: Yeah. That's fine.

21 THE COURT: All right.

22 Q. (By Mr. Slater) Do you have an opinion
23 as to whether or not it was appropriate or
24 inappropriate for Ethicon to sell the device
25 without studying what you just described with the

1 **arms and the cannulas?**

2 MS. JONES: Objection, Your Honor.

3 Form and foundation.

4 MR. BALL: And relevancy.

5 MS. JONES: And relevance.

6 MR. SLATER: And relevancy? We
7 have a negligence claim.

8 THE COURT: I'll let her answer
9 one time. That's it.

10 MR. SLATER: All right. Thank
11 you, Your Honor. I wasn't sure.

12 **Q. (By Mr. Slater) Okay. You can answer.**

13 A. Okay. It was inappropriate for Ethicon
14 to put this product and procedure on the market
15 without ever studying how this cannula system
16 would affect the mesh placement and incur safety
17 risks to women.

18 **Q. Okay. I'm now going to hand you a**
19 **document, Dr. Weber, marked as P1660. I'm going**
20 **to give copies to counsel.**

21 **And Dr. Weber, let me first, as a**
22 **foundation, ask you: Do you know what this**
23 **document is? Have you reviewed this?**

24 A. Yes.

25 **Q. And what --**

1 It's dated what date?

2 A. It is dated September 6th, 2006.

3 Q. And it says "Peter Meier" on the front.

4 Do you know who Peter Meier is?

5 A. Yes.

6 Q. Who is Peter Meier?

7 A. Peter Meier was a senior research
8 engineer at Ethicon.

9 Q. And is this document of significance to
10 you in supporting your opinions?

11 A. Yes.

12 Q. Okay. What I'd like to ask you to do --
13 and I'd like to put up Page 14.

14 Page 14 is up on the screen. Can you
15 tell the jury: Is that of significance to you in
16 supporting your opinions?

17 A. Yes.

18 Q. Why is that?

19 What is being shown, please?

20 A. So what is being shown is the Prolift
21 mesh implant, and this is something that was used
22 in a cadaver lab.

23 Q. Keep your voice up or get closer to the
24 mic, please.

25 A. I'm sorry.

1 So this was used in a cadaver lab, where
2 Ethicon was looking for the opinion of surgeons,
3 and in particular, in comparison between two
4 different types of meshes. One you can see
5 identified here as UltraPro, "UP," and the other
6 one which is the Gynemesh PS mesh which is the one
7 that's in the Prolift procedure.

8 **Q. And what was shown by this cadaver lab?**
9 **What was learned? What information is there?**

10 A. So they experienced that the UltraPro
11 handled better with the Prolift instruments. They
12 thought it might be too weak because the arms were
13 torn, but it felt very soft in place in comparison
14 to the Gynemesh PS in the Prolift procedure. No
15 crumpling of the arms.

16 **Q. What does that mean?**

17 A. So that means, like we saw in the video,
18 when the arms are pulled through the cannula,
19 they're crunched and roped and crumpled, and it
20 was this surgeon's experience that that was less
21 of an issue with UltraPro but worse of an issue
22 with the Gynemesh PS which is in the Prolift.

23 **Q. And now what I'd like to do is turn to**
24 **Page 22, and just very quickly, what is this page**
25 **telling us? Is this significant to you?**

1 A. Yes.

2 Q. And what is it telling us, real quick?

3 A. So this is a comparison in vitro, now --
4 so that means in the lab, not a cadaver kind of
5 testing -- of a comparison, again, between the
6 UltraPro mesh and the Gynemesh PS mesh that was in
7 the Prolift.

8 Q. And what information is there of
9 significance to you?

10 A. So on all of these characteristics that
11 they were studying, Gynemesh PS mesh turned out
12 worse than the UltraPro.

13 Q. Now, with regard to Ethicon's knowledge
14 of the UltraPro, as we've seen here, I want to ask
15 you --

16 We've seen a bunch of documents during
17 trial -- you're aware of that? -- with regard to
18 this subject?

19 A. Yes.

20 Q. We're not going to go through those
21 documents again because we know we've seen them,
22 but you've read all those documents and relied on
23 them?

24 A. Yes, I have.

25 Q. And with regard to the -- the story of

1 UltraPro, do you have an opinion as to what
2 Ethicon should have done based on its knowledge of
3 its scientists with regard to the properties that
4 they believed UltraPro had, compared to the
5 Gynemesh?

6 MS. JONES: Objection, Your Honor.
7 One, no foundation.

8 THE COURT: I'll sustain it
9 without some foundation for it.

10 MR. BALL: Your Honor, if I could
11 expand on that just a little bit.

12 THE COURT: All right.

13 MR. BALL: He is asking her to say
14 what a company should have done. She is a former
15 medical doctor and she's not had -- does not have
16 expertise or qualifications to talk about what a
17 company should have done.

18 MR. SLATER: I'll rephrase the
19 question, Your Honor.

20 THE COURT: If you would.

21 Q. (By Mr. Slater) The people who made the
22 decisions as to whether or not the Prolift would
23 go on the market with Gynemesh, were they
24 gynecologists?

25 A. Yes.

1 Q. In fact, the doctor who was in charge of
2 the decision-making at the time the Prolift went
3 on the market was -- is Dr. Owens, a gynecologist?

4 A. Yes.

5 Q. She had four years of experience outside
6 of her residency at that time?

7 A. Yes.

8 Q. As you compare Dr. Owens, four years out
9 of her medical residency, compared to you, would
10 it be fair to say you have a little bit more
11 experience and knowledge in the field than a
12 fourth year doctor would have?

13 A. Yes.

14 Q. And that was the person who made the
15 decision to keep it on the market and put it on
16 the market?

17 MS. JONES: Objection, Your Honor.

18 THE COURT: Well, only if she
19 knows that's who did it.

20 Q. (By Mr. Slater) It was -- who -- was it
21 Dr. Owens who signed off to allow this to be sold?

22 MS. JONES: Objection, Your Honor.
23 Misrepresents the evidence.

24 MR. BALL: And no foundation.

25 MS. JONES: No foundation.

1 Q. (By Mr. Slater) Was it the job of the
2 medical affairs director to sign various documents
3 attesting that the risks were outweighed by the
4 benefits and it could be sold?

5 A. Yes.

6 Q. And have you learned that from reading
7 the depositions, for example, of Charlotte Owens?

8 A. Yes.

9 Q. And she testified to that?

10 MS. JONES: Objection, Your Honor.
11 That -- she cannot comment on the testimony of
12 another witness. Objection.

13 THE COURT: I'll let it go to that
14 extent, but we won't go into anything else that
15 she said or thought.

16 Q. (By Mr. Slater) Let me ask it this way:
17 Have all of the witnesses in the case expressed
18 whether or not medical affairs directors have to
19 sign off before a product like the Prolift can be
20 marketed?

21 MS. JONES: Objection, Your Honor.

22 THE COURT: Sustained. I don't
23 know how they do that internally and that kind of
24 thing.

25 Q. (By Mr. Slater) Did you learn from the

1 **depositions how it works internally at Ethicon?**

2 MS. JONES: Objection, Your Honor.

3 THE COURT: That's right back to
4 the same thing. Sustained.

5 **Q. (By Mr. Slater) Do you have an opinion**
6 **as to whether or not Ethicon should have been**
7 **selling Gynemesh when they had this knowledge**
8 **about UltraPro --**

9 THE COURT: I think that's been
10 asked, hasn't it?

11 **Q. (By Mr. Slater) -- as a medical affairs**
12 **director?**

13 THE COURT: Except for that last
14 two words, I think that's been asked and answered.

15 MR. SLATER: That's all I'm
16 asking.

17 MS. JONES: And I object, Your
18 Honor, to Dr. Weber offering this opinion --

19 THE COURT: Well, I think it's
20 been asked and answered --

21 MS. JONES: -- without
22 qualification and foundation.

23 THE COURT: -- and so I'm going to
24 say, folks, I think that you heard that once --
25 everybody is nodding yes.

1 Okay. Go on. Let's move to something
2 else.

3 Q. (By Mr. Slater) I'm going to go into
4 some areas talking about risks and complications.
5 I want to ask you a foundational question.

6 In forming your opinions, are you relying
7 on testimony which would establish whether or not
8 Ethicon knew the risks and complications of the
9 Prolift when they launched it?

10 A. Yes.

11 Q. And what is that?

12 A. That is that they knew the risks --

13 MS. JONES: Objection, Your Honor.

14 I --

15 MR. BALL: That's the state of
16 mind.

17 MS. JONES: That goes directly to
18 the state of mind --

19 THE COURT: State of mind.

20 MS. JONES: -- and it's --

21 MR. SLATER: It's factual, Your
22 Honor. It's an admission by the corporate rep
23 that's been agreed to to be played.

24 I mean, I could play it to the jury right
25 now. I'm trying to save time. I don't know how

1 that's not --

2 MR. BALL: Can we approach again,
3 Your Honor?

4 THE COURT: Sure.

5 (Counsel approached the bench and
6 the following proceedings were held outside the
7 hearing of the jury:)

8 MR. BALL: If he's got testimony
9 about what somebody knew or didn't know, then play
10 the testimony. This is not the province of this
11 witness to come in and say what Ethicon knew or
12 didn't know.

13 THE COURT: That's true.

14 MR. BALL: It's not the province
15 of --

16 (Court reporter interruption.)

17 MR. SLATER: Relax. Please. Take
18 it easy. She's an expert witness. Your whole
19 objections to the other witness was, "Wait for the
20 expert to come in and talk about the facts."

21 Your Honor, my understanding is that the
22 expert can lay a foundation for opinions they're
23 going to give. Dr. Hinoul is going to testify to
24 this jury.

25 Look, I could play the testimony -- let

1 me please talk.

2 MS. JONES: I'm just trying to
3 tell you that you're talking so loud that the
4 jury --

5 THE COURT: Yeah. I wish you'd
6 keep it down a little.

7 MR. SLATER: Well, I can't get
8 past that (indicating).

9 THE COURT: Get over here. Okay.

10 MR. SLATER: Your Honor, they are
11 seriously objecting to my expert telling this jury
12 that she knows as a fact, based on testimony
13 that's already been agreed to be played, that the
14 corporate rep said they knew all the risks on day
15 one and they don't want to let her say that and
16 then testify about the risks?

17 I mean -- I mean, they are doing anything
18 they can to obstruct. I've never -- I've never
19 seen anything like this.

20 I could go play the testimony. If they
21 want, I'll play the clip. I'll do it. If they're
22 challenging the testimony, they know he gave the
23 testimony. I mean, do they want her not to be
24 able to say what she's relying on?

25 MR. BALL: I've never seen

1 anything like this either, okay?

2 MR. SLATER: Well --

3 MR. BALL: And the question is

4 supposed to be "Do you have an opinion?"

5 "Yes."

6 And then she can say, "What's the basis

7 of your opinion?"

8 "Well, in my opinion company witness

9 testimony supports that." Period. This is not --

10 MR. SLATER: Shouldn't she say

11 what that --

12 MR. BALL: Excuse me.

13 MR. SLATER: Why are you pointing

14 at me?

15 Shouldn't she say what the testimony is

16 so the jury knows what she relied on?

17 MR. BALL: This is not supposed to

18 be -- this examination is not supposed to be the

19 platform for the closing argument. It's not

20 supposed to be the platform for putting everything

21 together. It's not the platform for saying what

22 Ethicon knew or didn't know.

23 He puts in the evidence piece by piece.

24 He doesn't use this as a summary witness to put

25 all this together in closing argument form and

1 that's what he's trying to do and that's what's
2 improper under the law.

3 MR. SLATER: I disagree fully.
4 I'm not trying to do a closing argument. Man,
5 take it easy. I'm --

6 THE COURT: Well, look, look,
7 look. Ask a question and ask her if she's got an
8 opinion on it, but don't go into the --

9 MR. SLATER: Okay.

10 THE COURT: -- deposition
11 transcripts to have her criticize the other
12 people.

13 MR. SLATER: I'll ask it that way.
14 That's cool.

15 THE COURT: All right. Mighty
16 fine.

17 MR. SLATER: I thought I was
18 taking the first step. Now I got you. I'll do
19 more like that.

20 (The proceedings returned to open
21 court.)

22 THE COURT: We're going to give it
23 another shot here.

24 Q. (By Mr. Slater) Dr. Weber, do you have
25 an opinion as to whether or not Ethicon was

1 knowledgeable about the risks and complications
2 associated with the Prolift when it was first
3 marketed?

4 Do you have an opinion on that question?

5 A. Yes, I do.

6 Q. And what is your opinion?

7 A. My opinion is that Ethicon knew of all
8 the risks of -- associated with the Prolift
9 product and procedure before launch.

10 Q. And do you rely on internal documents and
11 deposition testimony for that opinion?

12 A. Yes, I do.

13 THE COURT: Mighty fine.

14 Q. (By Mr. Slater) Okay. I'm just going to
15 put this up here.

16 A. Okay.

17 Q. We've just given you, Dr. Weber, Exhibit
18 P065. Is that a document that you are familiar
19 with?

20 A. Yes.

21 Q. And what is that document?

22 A. This is a report on mesh erosions that
23 was commissioned by Ethicon.

24 MS. JONES: Objection, Your Honor.

25 May we --

1 MR. SLATER: Let me ask a
2 foundational question.

3 THE COURT: Okay.

4 MR. SLATER: We'll get to that
5 right now.

6 Q. (By Mr. Slater) Dr. Weber, do you have
7 an opinion as to whether or not Charlotte Owens
8 was familiar with all of the risks and
9 complications stated in this document at the time
10 that she was signing off on the product in 2005?

11 MS. JONES: Objection, Your Honor.

12 THE COURT: All right.

13 MR. SLATER: What's the objection?

14 MS. JONES: She can't comment --
15 he's asking her about what was known to who.

16 THE COURT: Do you want to come
17 back up here and state it -- huh?

18 MR. BALL: It's repeated -- this
19 is improper under Missouri law to say what
20 somebody else knew. That is not this witness'
21 name.

22 He can ask that witness and he has
23 testimony from that witness, but you're not
24 supposed to ask one witness what another witness
25 knew.

1 Q. (By Mr. Slater) Do you have -- do you
2 have an opinion as to whether or not medical
3 affairs was knowledgeable about the risks and
4 complications described in this report about mesh
5 erosions?

6 A. Yes, I have an opinion.

7 Q. And what is your opinion?

8 A. My opinion is that Ethicon was
9 knowledgeable -- Ethicon medical affairs was
10 knowledgeable about the complications related to
11 mesh erosion.

12 Q. And were they knowledgeable, in your
13 opinion, about the complications described in this
14 document?

15 A. Yes.

16 Q. Is the basis for that deposition
17 testimony and internal documents from the company?

18 A. Yes.

19 Q. Okay. Now, this is authored -- it
20 looks -- Peter Meier, the same person who was on
21 the cover of the last PowerPoint?

22 A. Yes.

23 Q. And his title was principal scientist,
24 Johnson & Johnson Medical?

25 A. Yes.

1 Q. What I'd like to do, if I could, is turn
2 to --

3 What's the title of the document, first?

4 MS. JONES: Objection, Your Honor.

5 May we approach? I'm sorry --

6 THE COURT: Yes.

7 MS. JONES: -- but --

8 (Counsel approached the bench and
9 the following proceedings were held outside the
10 hearing of the jury:)

11 MS. JONES: This document is dated
12 November 2010.

13 THE COURT: Okay. Then it's --

14 MS. JONES: That's three years
15 after --

16 MR. SLATER: Every single risk in
17 this document was known to Charlotte Owens. I
18 have her deposition testimony. I asked her in the
19 dep, "Do you see this document?"

20 "Yeah."

21 "Did you know all the risks stated when
22 you were the medical affairs director in 2005?"

23 "Yes," she said. So -- so --

24 THE COURT: Huh?

25 MR. BALL: Then show that

1 testimony.

2 THE COURT: Yeah. Show it.

3 MR. SLATER: No, no, no, no. My
4 expert -- this document goes through chapter and
5 verse what happened to Mrs. Budke. This is the --
6 this is a --

7 THE COURT: Keep it down. Would
8 you --

9 MS. STRAUSS: I was just going to
10 say, I can hear you clear back at counsel table.

11 THE COURT: Would you please keep
12 it down?

13 MR. SLATER: This document goes
14 through, chapter and verse, the complications that
15 happened to this woman, who died, and the medical
16 affairs director who let this go on the market
17 testified that she knew everything here, and now
18 they're saying just because the document was
19 written afterwards it can't come in?

20 She said she knew everything on -- at the
21 time. She was handling this in '05. So it's
22 not -- it doesn't matter if this document was
23 written right now. If she says she knew it, it
24 comes in. And Piet Hinoul testified they knew all
25 the risks on day one. It is not fair.

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1 MR. BALL: You know, it's all a
2 matter of how this is done, Your Honor.

3 THE COURT: What?

4 MR. BALL: It's all a matter of
5 how this is done.

6 THE COURT: Yes.

7 MR. BALL: All he has to say is
8 "Was this risk known at the time it went on the
9 market?"

10 "Yes."

11 "Was this risk -- was this risk known in
12 the medical community at the time it went on the
13 market?"

14 MR. SLATER: Well, I'd like to
15 show this document is written by an Ethicon
16 principal scientist in damaging language against
17 them --

18 THE COURT: How long -- how long
19 are you going to pursue that? I mean, how many --

20 MR. SLATER: This document?

21 THE COURT: Yeah.

22 MR. SLATER: When you see what's
23 in here, it's going to astound you. It tells the
24 life and death of Joan Budke, the mesh
25 complications that she had, the infections. It

1 lists the same infections she got.

2 MS. STRAUSS: This argument is too
3 loud. I can hear it --

4 THE COURT: I understand that it
5 is and that's why I'm trying to get y'all away
6 from here.

7 MR. SLATER: Your Honor, I have
8 the right to go through this document as long as I
9 need to to establish my case.

10 This is a critical document and the
11 medical affairs director said she knew all these
12 complications. So how can they try to keep it
13 out? They knew it and they ignored it. That's
14 the heart of this case.

15 MS. JONES: Your Honor, this
16 document is dated -- this document is dated
17 November of 2010.

18 THE COURT: Yes.

19 MS. JONES: It includes a
20 summary --

21 MR. SLATER: I'm not using any of
22 that.

23 MS. JONES: Well --

24 MR. SLATER: I'm not using the
25 medical --

1 THE COURT: If you use anything
2 after the date of her death that's in that from --

3 MR. SLATER: She testified -- I
4 put this document in front of her and she
5 testified she knew it all in '05. The medical
6 affairs director.

7 THE COURT: Okay. '05 is fine. I
8 just said I don't want to get into anything after
9 the date of her death on that.

10 MR. SLATER: No. The document was
11 written in 2010 but she testified she knew it all
12 in '05, that there's nothing in here that wasn't
13 known.

14 MR. BALL: Your Honor, he just
15 said he's got her testifying -- Charlotte Owens'
16 testimony to this, so put on Charlotte Owens --

17 MR. SLATER: No. My expert can
18 rely on that. I don't have to play Charlotte
19 Owens' entire testimony.

20 THE COURT: Was she here when --

21 MR. SLATER: Charlotte Owens?
22 Yeah. Charlotte Owens was the worldwide medical
23 director.

24 THE COURT: I know who she is. I
25 said was your witness there when she testified.

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1 MS. JONES: No.

2 MR. SLATER: At the deposition?

3 THE COURT: Yeah.

4 MR. SLATER: Was she sitting in
5 the room?

6 THE COURT: I don't know. I
7 mean --

8 MR. SLATER: But she's seen the
9 deposition. She's allowed to rely on the
10 deposition testimony.

11 MR. BERGMANIS: This is what
12 experts do.

13 MR. SLATER: Experts --

14 THE COURT: I understand that.

15 MR. SLATER: Yeah. Experts --

16 THE COURT: I understand that.

17 MR. SLATER: I'm being held to --

18 THE COURT: What?

19 MR. SLATER: Nothing.

20 MS. JONES: My objection, Your
21 Honor, is to the use of this document, which is
22 dated 2010, to which is attached a series of --

23 MR. SLATER: I'm not using that, I
24 just told you.

25 MS. JONES: That's all right.

1 It's part of the document.

2 MR. SLATER: I'm not using that.

3 I'm using the text. I'm just --

4 THE COURT: Are you going to try
5 to put that whole document in?

6 MR. SLATER: I won't put the --

7 THE COURT: All right.

8 MR. SLATER: -- literature
9 summary. Just the text.

10 THE COURT: All right. Then let's
11 go back, then, but I'm going to bind you to that.
12 Okay?

13 MR. SLATER: I'm with her. I'm
14 happy. Talk to her.

15 (The proceedings returned to open
16 court.)

17 THE COURT: Okay, Mr. Slater.

18 MR. SLATER: Sorry, Judge.

19 Q. (By Mr. Slater) Okay. Doctor --
20 Dr. Weber, what I'd like to do now is turn to
21 Page 8, the section -- or Page 7, actually, the
22 section titled "2.2 Mesh-Related Complications."

23 A. Yes.

24 Q. And this entire document, are you relying
25 on this for your opinions in this case?

1 A. Yes.

2 Q. Now, we'll look at the first paragraph.

3 And pull that out, please.

4 And what I'd like to do is start with the
5 first sentence and I'll read it for the jury and
6 then ask you a question.

7 It says, "While the" --

8 And this was written by an Ethicon
9 scientist, correct?

10 A. Yes.

11 Q. "While the advantages of synthetic meshes
12 are evident, specific concerns regarding their use
13 which can seriously compromise the patient's
14 health and quality of life have been reported in
15 the literature. Once the mesh material has been
16 implanted in the body, the host immune system
17 reacts to the introduction of this foreign
18 material and covers the material with a biofilm.
19 This triggers a complex series of host-to-implant
20 material interaction."

21 Can you tell the jury what that means,
22 please?

23 A. Okay. So that -- what that means is,
24 when a permanent synthetic mesh is implanted, the
25 body recognizes that as a foreign object, and the

1 immune system is trying to do its job of -- of
2 eliminate or, if it can't eliminate, at least
3 protect the body from this foreign body.

4 Q. Now, a little further down in the
5 paragraph, it refers to an acute inflammatory
6 phase and a chronic inflammatory phase resulting
7 in foreign body reaction.

8 What does that mean, acute versus chronic
9 inflammatory phases?

10 A. Okay. So that's just two steps in this
11 inflammatory phase.

12 The first step is called the acute, so
13 the white blood cells are rushing in, they're
14 trying to scoop up any bacteria that have come in
15 with the implant. And the fact of the matter is,
16 because the mesh is implanted through the vagina
17 and the vagina has lots of normal bacteria that
18 live there, there are bacteria that come in with
19 the mesh. Completely unavoidable.

20 So in the acute phase, the body's trying
21 to use the immune system to scoop up those
22 bacteria and try to prevent them from causing
23 trouble.

24 And then it moves into a chronic phase
25 where a similar kind of thing is going on. The

1 white blood cells are working against the implant,
2 the foreign body. They release products that can
3 be toxic to nearby cells, so there can be another
4 reason for ongoing cell death and tissue damage.

5 Q. Let's go -- let's go to the next
6 paragraph.

7 A. Right.

8 Q. And just -- actually, I just want to make
9 sure, "chronic inflammatory phase," does that
10 "chronic" mean it goes on indefinitely?

11 A. Yes.

12 Q. The second paragraph, the second sentence
13 says, "Mesh material related adverse events
14 include infections, erosions, extrusions, mesh
15 shrinkage, vaginal granulation tissue, sinus
16 formation, abscess, fistulas," all those things.

17 Do you see where I just read?

18 A. Yes.

19 Q. With regard to infection, erosion,
20 extrusion, mesh shrinkage, abscess, and fistula,
21 do you have an opinion as to whether Ms. Budke --
22 Mrs. Budke experienced those complications?

23 A. Yes, I have an opinion.

24 Q. And what's your opinion?

25 A. My opinion is that she suffered from all

1 of those complications and others.

2 Q. Let's look at the third paragraph.

3 It says, "Various pathogens, including
4 gram-positive and gram-negative aerobic and
5 anaerobic bacteria such as" -- and I'm going to
6 try to pronounce these.

7 Actually, you know what? I'm going to
8 ask you to pick up there.

9 A. Okay. "Morganella morganii, Actinomyces,
10 Bacteroides melanginococcus [sic]."

11 Q. And the rest of the sentence says those
12 bacteria have also been implicated as causative
13 organisms associated with vaginal mesh infections.

14 Is that of significance to you in this
15 case?

16 A. Yes.

17 Q. Why?

18 A. Because Mrs. Budke had a vaginal mesh
19 infection. She had a pelvic abscess. Bacteroides
20 was identified as one of the organisms that was
21 part of the pelvic abscess.

22 Q. Let's go to the next page, Page 8, at the
23 top.

24 It says at the very top, the paragraph
25 just below those types, "Of all these

1 complications, mesh erosion remains a major cause
2 of concern in the use of meshes in pelvic
3 reconstructive surgery."

4 I just want to stop there.

5 Is that something you'd actually agree
6 with?

7 A. Yes. A major cause of concern.

8 Q. And then it talks about the factors
9 contributing to the wide range of erosion rates,
10 and at the bottom it says, "The specific
11 properties of the mesh material, such as pore
12 size, stiffness, elasticity, and basic tissue
13 compatibility."

14 I'm going to stop there and ask you:
15 Have you studied those aspects of the Prolift in
16 your work in this litigation?

17 A. Yes.

18 Q. Have you studied internal documents and
19 deposition testimony with regard to Ethicon's
20 knowledge of those things?

21 A. Yes.

22 Q. Have you studied the clinical and
23 peer-reviewed literature on those subjects to
24 understand what those -- the impact of those
25 aspects of the mesh has on the safety of the mesh?

1 A. Yes.

2 Q. And with regard to those things -- pore
3 size, stiffness, elasticity, and basic tissue
4 compatibility -- do you have an opinion as to
5 whether, with the Prolift, those aspects of the
6 mesh are safe or unsafe?

7 MS. JONES: Objection, Your Honor.
8 Qualifications.

9 THE COURT: I'm going to overrule
10 that.

11 Go ahead.

12 Q. (By Mr. Slater) You can answer.

13 A. Yes. My --

14 Q. And what -- and what is your opinion?

15 A. My opinion is that the Prolift mesh is
16 unsafe.

17 Q. And those -- and with regard to those
18 aspects that I just asked you about, do you have a
19 specific opinion as to those?

20 A. Yes, I do.

21 Q. What?

22 A. That based on those characteristics of
23 the Prolift mesh, the Prolift mesh is unsafe.

24 Q. Well, let's look at Paragraph 3 now,
25 "Etiology of Mesh Erosions." That means cause of

1 mesh erosions?

2 A. Yes.

3 Q. And it says in the second sentence, "Mesh
4 erosion refers to the breakdown of internal tissue
5 caused by irritation or infection elicited by" --
6 "elicited by the patient's immune system when a
7 foreign material such as synthetic mesh is
8 introduced into the body. The exposed mesh may
9 erode the vagina, urethra, rectum, bladder, or
10 bowel."

11 Do you see that?

12 A. Yes, I do.

13 Q. And is that significant to you with
14 regard to this case?

15 A. Yes.

16 Q. Why?

17 A. Because that's exactly what happened to
18 Mrs. Budke. She had a mesh erosion that -- that
19 existed for months that, as we've been talking of,
20 is a result of the body's response to the foreign
21 body in its attempts to protect the whole body
22 from this -- the adverse reactions to this
23 implant.

24 Q. The next paragraph says, "An accurate
25 erosion rate is difficult to determine, because

1 mesh erosions can occur at variable time intervals
2 after placement ranging from 6 weeks to 7 years."

3 Is that significant to you?

4 A. Yes.

5 Q. Why?

6 A. It's significant because it indicates
7 that mesh erosion can occur at a time remote from
8 the indexed surgery, the initial surgery, and
9 although this limits the time frame to seven
10 years, we know that's not true. It's a lifelong
11 risk that a woman carries as soon as she has this
12 mesh implanted in her body.

13 Q. Let's turn the page to Page 9 where it
14 discusses the "Surface Area of Mesh."

15 And that Paragraph 9 -- on Page 9, I
16 mean, "Surface Area of Mesh," let's pull that up.

17 It starts out -- and I'm going to ask you
18 a question about this -- "The amount of foreign
19 body reaction increases with the amount of surface
20 of the foreign material being exposed to the
21 host."

22 Is that significant to you?

23 A. Yes.

24 Q. Why is that -- does that relate to the
25 Prolift?

1 A. Yes, it does.

2 Q. Please explain to the jury why that does.

3 A. Like we saw in the animation video, at
4 the end of the operation you saw how much mesh is
5 left in the woman. That large central body that
6 goes from one side of the pelvis to the other and
7 those four mesh arms that come out through those
8 previously uninvolved areas in the hip and the
9 thigh. That's an enormous amount of mesh for the
10 body to try to cope with.

11 Q. At the bottom of that paragraph, it says,
12 "Therefore, a thinner mesh combined with less
13 material per given area reduces the risk of
14 erosion."

15 With regard to that sentence, does
16 UltraPro fit that characteristic, compared to the
17 Prolift mesh?

18 A. Yes.

19 Q. Let's go to Page 11. Towards the middle
20 of the page, it says, "Several commercially
21 available all-inclusive kits."

22 Do you see that?

23 A. Yes.

24 Q. I'd like to bring up that paragraph and
25 highlight the last sentence of that paragraph. It

1 **says, "Large randomized trials of conventional**
2 **surgery versus mesh insertion is necessary to**
3 **determine the long-term anatomical and functional**
4 **efficacy of these kits."**

5 **Do you see that?**

6 A. Yes, I do.

7 **Q. Is that significant to you?**

8 A. Yes.

9 **Q. Why?**

10 A. Because like we talked about a little bit
11 earlier, the only way you can draw a conclusion as
12 to cause and effect is with a randomized trial.

13 So for anyone to say that the Prolift is
14 safe and effective compared to traditional
15 surgery, you need a randomized trial.

16 And "long-term" is very important because
17 of what we just talked about. Once the mesh is
18 implanted, the woman is subject to mesh
19 complications for the rest of her life. So if you
20 only look at a very short-term follow-up, things
21 might look okay, but when you look longer, it
22 turns out, no, they're not okay at all.

23 **Q. With regard to that statement, do you**
24 **have an opinion as to whether or not a study of**
25 **the rigor and the comprehensiveness that you would**

1 think would be necessary to adequately study the
2 Prolift, was any such study ever performed?

3 A. No.

4 Q. Is that significant to you?

5 A. Yes.

6 Q. Why?

7 A. Because in failing to perform a study of
8 that nature, the Prolift was put on the market
9 without the kind of evidence and information that
10 women need to make a decision, balancing the risks
11 and benefits, is this a good choice for me. So
12 they don't have that information.

13 That's what we call experimental. That's
14 when you need to do a clinical study. Because if
15 you don't do a clinical study at that point, the
16 women who are getting the procedure are being
17 experimented on anyway. They just don't know it
18 and they're not given permission for it. They
19 have not given permission for it.

20 MS. JONES: Objection, Your Honor.
21 I think this goes --

22 THE COURT: Sustained. I'll
23 sustain that.

24 MR. SLATER: Just to the last
25 part, Your Honor?

1 THE COURT: Yeah.

2 MR. SLATER: I just don't want to
3 reask the first part.

4 THE COURT: Yeah, yeah, yeah.

5 MR. SLATER: Thank you.

6 Q. (By Mr. Slater) Let's go to Page 14, the
7 section on "Diagnosis of Mesh Erosions," and we'll
8 go to Section 5.2, "Diagnosis."

9 A. Yes.

10 Q. Pull that paragraph up, please.

11 And it says, the second half,

12 "Intravaginal visualization" --

13 And what does that mean?

14 A. That just means you can see it inside the
15 vagina.

16 Q. -- "of a foreign body at the apex" --

17 And that's the top of the vagina?

18 A. Correct.

19 Q. -- "or elsewhere implies intravaginal
20 mesh erosion or/and infection. Furthermore,
21 eroded meshes through the vagina may indicate a
22 simultaneous infection, based not only on the
23 presence of vaginal discharge or consolidation of
24 inflammatory tissue around the mesh, but also on
25 the type of mesh applied."

1 Is that important to you in your
2 opinions?

3 A. Yes, it is.

4 Q. Why?

5 A. Again, that's because that's exactly what
6 happened to Mrs. Budke. She developed a mesh
7 erosion and then it became infected from the
8 bacteria that live in the vagina normally.

9 So you have this mesh erosion. It's a
10 raw, open spot in the vagina, and the bacteria get
11 in there. That's just what they do. And then
12 they initiate this infection and the inflammatory
13 mass that's described here.

14 Again, the body's just trying to respond
15 appropriately to the infection, but unfortunately
16 what's happened -- what happens sometimes in the
17 body's efforts is it actually makes matters worse.

18 So you've got this inflammation, all this
19 swelling, it blocked off her ureters, she had
20 kidney failure --

21 MS. JONES: Your Honor, I'm --

22 THE COURT: It's going far beyond
23 the question that was asked.

24 MR. SLATER: All right. I'll ask
25 the next question.

1 Q. (By Mr. Slater) Let's look at
2 Paragraph 6.0, "Management of Mesh Erosions," on
3 Page 15.

4 A. Yes.

5 Q. And Doctor -- and Peter Meier, the
6 Ethicon scientist, writes -- let's pull that up --
7 "The management of erosions is dependent on the
8 amount of material exposed, the type of material,
9 and associated infection. There is limited data
10 on the optimal cost-effective management of mesh
11 erosion and infection."

12 I want to stop there.

13 Is that significant to you?

14 A. Yes.

15 Q. Why?

16 A. Again, this is exactly what Mrs. Budke
17 had, and this is years after the Prolift had been
18 put on the market.

19 Limited data. Well, whose fault is that?
20 Ethicon is responsible for --

21 THE COURT: Stop.

22 MS. JONES: Your Honor, move to
23 strike.

24 THE COURT: I'll strike all of
25 that.

1 MS. JONES: And I'd ask that the
2 jury be instructed --

3 THE COURT: Disregard that last
4 statement and the answer that was given and let's
5 start over, and please, let's stay with the --

6 Q. (By Mr. Slater) Please explain from a
7 scientific and a medical standpoint why that's
8 significant.

9 A. Okay. So from a medical and a scientific
10 standpoint, it's an -- it's significant because
11 doctors don't have the kind of information they
12 need to know how to best care for women when they
13 show up -- when they come in with these very
14 important complications related to the mesh.

15 Q. It says just below that, "surgical
16 treatment which involves drainage of abscesses,
17 partial or complete removal of the mesh."

18 Is that significant here?

19 A. Yes.

20 Q. Is that what happened to Mrs. Budke?

21 A. It was attempted. The -- the complete
22 removal of the mesh was attempted. And again, as
23 we've already discussed, that never was possible.
24 She was never -- the doctors were never able to
25 remove all the mesh in Mrs. Budke.

1 Q. Let's go to Section 6.2, the first
2 paragraph, the last sentence.

3 "When the upper" -- "When the upper
4 portion of the mesh is infected, removal of the
5 entire mesh is required through a transvaginal or
6 abdominal approach."

7 Is that significant?

8 A. Yes.

9 Q. Why is that significant in this case with
10 Mrs. Budke?

11 A. That the -- the idea that the removal of
12 the entire mesh can even be accomplished.

13 You know, like we were just saying, it
14 can't be accomplished. The mesh is infected.

15 The ordinary medical thing to do would be
16 to remove the foreign object that's contributing
17 to this infection and making it resistant to
18 treatment, and that cannot be accomplished.

19 Q. Let's go to the next paragraph, the very
20 last sentence.

21 It says, "Residual infected mesh after a
22 failed partial excision requires a second excision
23 generally via laparotomy" --

24 That's actually cutting open the tissue?

25 A. Actually that's through the abdomen,

1 right. An abdominal incision.

2 Q. -- "and usually represents a difficult
3 surgical dilemma, as recurrent erosions are
4 associated with chronic morbidity including
5 chronic infection, sinus tracts, abscess, and
6 fistula formation."

7 Is that description significant to you in
8 this case with Mrs. Budke?

9 A. Yes, it is.

10 Q. Why?

11 A. Because that's exactly what happened.
12 This cascade of complications where she had an
13 initial mesh excision in January, another attempt
14 at excising more mesh in March, and -- to treat
15 the abscess, and -- and later developed a fistula,
16 the vesicovaginal fistula that connected the
17 bladder to the vagina, so that she was unable to
18 control her urine at all.

19 She was constantly leaking urine that
20 contributed to more tissue damage in the area.
21 She had sacral ulcers that were unable to heal, at
22 least in part because of this condition because of
23 the fact that urine was under her all the time and
24 she had no way of controlling that.

25 Q. When it refers to a chronic infection, is

1 **that significant here?**

2 A. Yes.

3 **Q. Why?**

4 A. Because of the presence of the mesh, it
5 makes it very difficult to treat the infection,
6 and that's why the recommendation is to remove the
7 entire mesh, even though we already know that's
8 not possible, because the body can't resolve an
9 infection -- or at least it makes it very much
10 more difficult -- when a foreign body is in place.

11 So that's what a chronic infection is,
12 where antibiotics alone can't take care of the
13 problem, and the -- you know, the idea that you
14 need to try to remove the mesh, even though that's
15 not possible.

16 **Q. Okay. We're going to go to the next**
17 **document.**

18 **This is Exhibit P1755. Is this a**
19 **document you're familiar with, Dr. Weber?**

20 A. Yes.

21 **Q. Is it a document that you rely on, in**
22 **part, for your opinions in this case?**

23 A. Yes.

24 THE COURT: Yes?

25 MS. JONES: Your Honor, once

1 again, this is a 2011 document that postdates the
2 events in this case by two or three years. I
3 would object.

4 MR. SLATER: We have -- we have
5 the same foundation as we pointed out up there,
6 that it's been acknowledged they knew all these
7 things.

8 THE COURT: Prior to.

9 MR. SLATER: Yes. Every single
10 risk.

11 MS. JONES: Well, wait.

12 MR. BALL: Your Honor, may we
13 approach?

14 THE COURT: Sure.

15 MR. SLATER: You know what, Your
16 Honor? In the interest of time, I just won't use
17 the exhibit.

18 THE COURT: All right. Asked and
19 answered. I think we're getting lots of
20 information maybe.

21 Okay. If you can move on to something
22 else.

23 MR. SLATER: Yeah. No problem.

24 Q. (By Mr. Slater) Okay. Dr. Weber, before
25 we put this up, this is a document that has been

1 prepared with regard to the Gynemesh PS study,
2 correct?

3 A. Yes.

4 Q. Would you tell the jury what the Gynemesh
5 PS study was?

6 A. Okay. So Ethicon sponsored a study to
7 look at what happens to women who have the
8 Gynemesh PS mesh implanted either through the
9 abdominal approach or transvaginally.

10 Q. And what was the purpose of this study?

11 A. To -- well, to report on the outcomes, as
12 I mentioned, of using Gynemesh PS mesh to
13 encourage doctors to become mesh users.

14 Q. Did you actually read the study
15 reports -- we'll start with those -- the reported
16 results of this study of the mesh?

17 A. Yes.

18 Q. Did you do more to get information about
19 this actual study?

20 A. Yes, I did.

21 Q. Please tell the jury what you did to
22 evaluate the data in the Gynemesh study, please.

23 A. So I evaluated the study protocol and all
24 the data collection forms for the women that were
25 enrolled in the study.

1 **Q. What does that mean, "the data collection**
2 **forms"?**

3 A. So that's what we call the raw data. So
4 that's where the information has been transcribed
5 from the woman's medical chart or if it's a
6 questionnaire that she filled out herself. That
7 becomes part of the package that we call a case
8 report form.

9 And then each visit that the woman has
10 has another set of case report forms with that
11 information, and maybe if the questionnaires were
12 repeated.

13 So for every patient for every visit that
14 was involved in this study, I reviewed the case
15 report forms myself.

16 **Q. Did that take a while?**

17 A. Yes, it did.

18 **Q. Okay. What I'll do is put up Exhibit**
19 **P1768 now. Tell the jury what this document is**
20 **when it gets up on the screen.**

21 A. Yes.

22 **Q. Please tell the jury what we're looking**
23 **at here.**

24 A. Okay. So what I did, after I analyzed
25 all the data myself from the case report forms, is

1 then I set out to summarize the results myself.

2 And what I found was that there was a
3 drastic difference between the results that I
4 found, when I analyzed the data myself, and what
5 Ethicon had reported to the scientific community.

6 **Q. And take us through that, please, and**
7 **tell us line by line what you found and what these**
8 **different values were, based on your assessment of**
9 **the actual records.**

10 A. Right.

11 So as you can see, the first column just
12 describes the characteristic.

13 The second column is what Ethicon said
14 happened.

15 The third column is what I found when I
16 went through those case report forms myself.

17 So mesh exposure, as you've -- excuse me,
18 as you've probably heard by now, is another name
19 for mesh erosion.

20 At one year, Ethicon claimed that 9.4% of
21 women had experienced a mesh erosion. What I
22 found actually was that 15.4% of women had
23 experienced a mesh erosion by one year.

24 **Q. Was that significant to you?**

25 A. Yes, it was.

1 **Q. Why?**

2 A. That's a very high rate. And like we
3 were talking about before, with short-term
4 followup, you're just getting a little snapshot of
5 what can happen to a woman when she has this
6 permanent mesh implant for the rest of her life.

7 So for 15% in only one year, when some
8 women are going to have this implant for 20, 30,
9 40 years, it becomes a matter of grave concern
10 that even within one year, the mesh complication
11 rates are so high.

12 **Q. And in the interest of time, I want to**
13 **now go to the prolapse recurrence rates.**

14 A. Yes.

15 **Q. Can you tell the jury what you found and**
16 **what's documented here?**

17 A. Yes.

18 So prolapse recurrence, like we talked
19 about before, is when the prolapse comes back
20 again.

21 And what Ethicon reported was that this
22 happened to 24% of women. Even that's not so
23 great. Again, with only one year of follow-up.

24 What actually happened was it was closer
25 to 34%. 33.8% of women had had a recurrent

1 prolapse by the time one year had elapsed.

2 Q. And that's of the total number of women
3 that are being -- that you counted?

4 A. That's right.

5 Q. And then you have a one-year vaginal
6 surgery prolapse recurrence rate. What does that
7 mean?

8 A. So as I mentioned, the study set out to
9 evaluate women who had the mesh placed abdominally
10 and then placed vaginally.

11 So Ethicon didn't even report these
12 people as separate groups, even though they're
13 very different operations. They have a very
14 different set of risks and benefits and outcomes.
15 You know, success as far as treating the prolapse
16 problem.

17 So they didn't report that at all, but
18 what I found was that 27.3% of women who had the
19 vaginal implantation of mesh had recurrent
20 prolapse within one year. And that's a very high
21 rate. That's a matter of concern.

22 Q. Who were the investigators for this
23 study?

24 A. The investigators for this study were
25 Ethicon consultants and preceptors, the doctors

1 who teach other doctors how to perform these
2 procedures, paid by Ethicon.

3 Q. Do you remember the names of some of
4 them?

5 A. Dr. Lucente. Dr. Murphy. Dr. Miller.
6 I think that's all I can remember right
7 now.

8 Q. In terms of the reports by Ethicon of the
9 number of patients studied and what the rates were
10 of these complications, were the reports
11 consistent or inconsistent even with one another?

12 A. They were inconsistent with one another.
13 This -- the results of this study were reported in
14 different venues at different professional society
15 meetings, and even that information wasn't
16 consistent. The numbers changed from -- from
17 meeting to meeting, and it certainly came nowhere
18 close to what I found when I analyzed the data
19 myself.

20 Q. The case report forms, the data
21 collection forms for the patients, do they have
22 sections where certain information is requested so
23 that it will be sure that an investigator will
24 know to look for certain things?

25 A. Yes.

1 Q. And is that important?

2 A. Yes, it is.

3 Q. Why?

4 A. Well, remember we talked about this a
5 little bit this morning when I went on to that
6 additional training in research study design?

7 It's like anything else, right? You only
8 get out what you put in. So after the study is
9 done and you say, "Gosh, I wish I'd remembered to
10 ask that question," you know what? It's too late.
11 You can't go back and get that.

12 So the key is to set that up from the
13 start, to know how to properly design a study so
14 that you capture the information that's critical
15 to your understanding of the risks and benefits of
16 what you're trying to study.

17 Q. Did the case report forms ask the doctors
18 to look and see if there was contraction of the
19 mesh?

20 A. No, it did not.

21 Q. Is -- do you have an opinion about
22 whether or not that was a good or a bad thing?

23 A. That was inappropriate. That's -- again,
24 if you don't ask the question, you're not going to
25 get the answer.

1 So from a scientific point of view, when
2 you're trying to understand the risks and benefits
3 of this vaginal mesh use -- or abdominal, for that
4 matter -- you have to include the items of
5 importance, the items that we know carry severe
6 clinical consequences when they occur, like mesh
7 con- -- mesh contraction.

8 **Q. Okay. What I'm going to do is we'll take**
9 **that one down and then I'm going to go -- just**
10 **flip back to Exhibit 1593, the professional ed**
11 **deck, and we'll look real quick at Page 16.**

12 THE COURT: While you're pulling
13 that up, I'd like to give them a break about
14 12:30, if you can kind of work it around that.

15 MR. SLATER: Anytime you want,
16 Judge.

17 THE COURT: Okay.

18 MR. SLATER: Whenever you think.
19 I'll -- well, whenever you give me the high sign.

20 THE COURT: All right.

21 **Q. (By Mr. Slater) All right. So we're on**
22 **Page 16, and this is the professional ed deck that**
23 **was used, for example, to train Dr. Simpson**
24 **about -- about the data on the mesh in the**
25 **Prolift?**

1 A. Yes, it was.

2 Q. And here they're talking about the
3 Prolene -- the Gynemesh Prolene Soft mesh, the
4 mesh material? The study you just told the jury
5 about?

6 A. Yes.

7 Q. And I'd like to look at the last line
8 there. It says 84% success rate, Stage 0 or 1 at
9 one year.

10 Do you see that?

11 A. Yes, I do.

12 Q. And based on your review of the actual
13 patient-level study data, do you have an opinion
14 as to whether that was accurate or inaccurate?

15 A. Yes.

16 Q. What's your opinion?

17 A. My opinion is that that is inaccurate.

18 Q. And what is the difference?

19 You don't have to quantitate it, but was
20 there more or less?

21 A. There were -- there was a lower rate of
22 success than what was claimed by Ethicon in their
23 professional education.

24 Q. Okay. Let's go to the next one now.

25 This is Exhibit P1754, for the record. And before

1 we put this up, Dr. Weber, this is a document with
2 regard to the French TVM study?

3 A. Yes.

4 Q. The jury's heard a little bit about it,
5 but just so that they know that you know what it
6 is, would you please tell the jury what that was?

7 A. Yes. So the TVM group, the French --
8 group of French doctors that you may have heard
9 were the ones who were instrumental in developing
10 the procedure that eventually became the Prolift
11 procedure, they were experimenting with different
12 mesh designs, cutout shapes, and different tools
13 and whatnot, to see if they could improve on the
14 prolapse repair procedures that had been done in
15 the past.

16 And so Ethicon sponsored a study of the
17 women who were undergoing this as a -- as a
18 prototype, an earlier version -- not the real
19 Prolift but an earlier version of what would
20 become the Prolift, and the French investigators
21 were involved and there were also investigators
22 involved in the United States.

23 Q. Okay. Let's put this up, P1754, please.

24 What are we seeing here, Dr. Weber?

25 A. Okay. So this is going to start to look

1 very familiar to you.

2 I went through all the data on these
3 patients to arrive at my own analysis and compared
4 that with what was reported by Ethicon.

5 **Q. And please show us what you found.**

6 A. So you can see at all of these times of
7 follow-up -- six months, one year, three years --
8 they underreported the number of women who
9 experienced a mesh erosion. In other words, they
10 didn't report the right number. It was lower than
11 what the correct number should have been.

12 **Q. And just let's go through it.**

13 **Starting at six months, what did you**
14 **find?**

15 A. 17.2%.

16 Again, at such a short duration of
17 follow-up, that is alarmingly high.

18 **Q. And you're saying 17.2% of the 87 women**
19 **who were there at six months had a mesh erosion?**

20 A. Yes.

21 **Q. At one year, what did you find and what**
22 **did Ethicon report?**

23 A. So Ethicon reported -- as you can see,
24 they reported it as if the mesh erosion rate went
25 down. They reported 14.9% at six months and then

1 9.2% at one year.

2 Q. How do you have less erosions at a year
3 than you had at six months?

4 A. The way you do that is if a woman had an
5 erosion that was treated and went away, they acted
6 like it didn't happen and they didn't count it
7 anymore. That's the way you get to have a lower
8 number at one year than at six months.

9 Q. And then you see the three-year rates.
10 They reported 14.4% and you found 23.5%?

11 A. Yes.

12 Q. I want to ask you -- I'm not going to
13 pull up the study report. We've seen it. We know
14 what it says.

15 With regard to these --

16 Well, we'll get to that, actually. I'm
17 going to get to that in just a second.

18 A. Okay.

19 Q. Let's try to get through this and we'll
20 go to the U.S. study report now, and then we'll
21 wrap it up in a few minutes. 1737.

22 Dr. Weber, what is this exhibit?

23 A. So this is what happened in the U.S. side
24 of the study. We just looked at what was
25 happening in the French side of the study, so this

1 is the U.S.

2 Q. And we see the figures, and just quickly
3 tell us what you found with regard to the reported
4 rates versus what you found when you went through
5 the actual documents yourself.

6 A. Yes. So as you can see, at each time
7 point -- and at three years it wasn't even
8 reported by Ethicon -- the number Ethicon reported
9 is much lower than what I found when I examined
10 the documents myself.

11 And you can see the same pattern between
12 six months and one year in what Ethicon reported,
13 where they said 9.5% of women were affected by
14 mesh erosion at six months, but only 6% were
15 affected at one year. Eight women at six months
16 and five women at one year.

17 And like we said before, the only way
18 that can happen is when a woman has had a mesh
19 erosion and it has resolved with treatment, or
20 whatever, and then Ethicon pretended it didn't
21 happen, they didn't have to count that --

22 MS. JONES: Objection, Your Honor.
23 That's an inappropriate comment.

24 THE COURT: Sustained. Would --

25 Q. (By Mr. Slater) Just rephrase it,

1 **Dr. Weber, please.**

2 A. Okay. Ethicon didn't count those mesh
3 exposures as something that had happened to women,
4 and that's how you get a lower number from six
5 months to one year.

6 **Q. What is good clinical practice in terms**
7 **of reporting adverse events? What does that mean?**

8 A. Okay. "Good clinical practice," even
9 though it doesn't sound like it, is a research
10 term -- oh, excuse me. Is a research term, okay?

11 And so what that means is that the
12 investigators are following the rules to protect
13 patients, first of all, because in any experiment
14 where women are voluntarily consenting to be
15 involved, patient safety is the most important
16 thing to protect, and rules as far as collecting
17 data appropriately so that you can analyze it, and
18 then rules as far as data analysis, so that in the
19 end people can trust your results.

20 If you follow all of the good clinical
21 practice guidelines in research, then your
22 research results are robust and people will be
23 able to rely on them.

24 **Q. Did Ethicon, in your opinion, follow good**
25 **clinical practices with regard to how they counted**

1 **adverse events?**

2 A. Not at all.

3 **Q. And for the reasons you've already**
4 **stated?**

5 A. Yes.

6 **Q. Exhibit 1752.**

7 THE COURT: Can we take the break
8 after this one?

9 MR. SLATER: Sure.

10 THE COURT: Go ahead.

11 **Q. (By Mr. Slater) Doctor, what is**
12 **Exhibit 1752?**

13 A. Okay. So this reports the findings of
14 the French part of the TVM study again, and this
15 time we're looking at prolapse recurrence.

16 So if prolapse came back in the women who
17 had gone through the TVM procedure, which stands
18 for "transvaginal mesh."

19 **Q. And the jury's heard this, so we've heard**
20 **what a primary endpoint is. That's -- that's the**
21 **point that was set up as either the -- as the**
22 **cutoff for success or failure?**

23 A. Yes.

24 **Q. We've heard the term "confidence**
25 **interval." If you would briefly tell the jury**

1 **what that means and why that's significant with**
2 **regard to those numbers on that page.**

3 A. Yes. So a confidence interval is another
4 statistical term.

5 When you have a group of women and you
6 measure something, you come up with an average.
7 So it's -- you know, you add everybody all up and
8 you divide them and you have an average number.

9 Now, what the confidence interval does is
10 put some limits around that average to tell you,
11 if you did this same study in another hundred
12 women, and another hundred women and another
13 hundred different women, and maybe you went to
14 Australia or whatever, then you would be 95 or 90%
15 confident that the average would fall within those
16 boundaries. Okay?

17 Does that make sense?

18 Okay. Good.

19 **Q. And with regard to the confidence**
20 **interval and the rates there, what is significant?**

21 A. Okay. So the confidence interval, as I
22 said, gives you a -- a lower and an upper bound
23 that you can be confident in, if you'd repeated
24 this study many times with different women, the
25 average would fall within that.

1 So that gives you -- I hate to keep
2 saying the word "confidence," but that's where it
3 got its name -- that you can rely on this as being
4 a number that's going to be true for a lot of
5 women. Even if you took many mother -- many other
6 women, studied them, then this average would be
7 true, and that they would fall somewhere within
8 this range.

9 **Q. And why was 20% of significance here?**

10 A. That was the cutoff that Ethicon chose in
11 their study design to say, "Okay, this -- if the
12 failure rate exceeds 20%, then that's too much of
13 a failure. That's not good enough and we should
14 stop there."

15 **Q. And what was the outcome here?**

16 A. So the outcome was that the recurrence
17 rate exceeded 20%, and when you look at -- the top
18 one is the 90 and the bottom is the 95. Both of
19 them exceeded 20% by quite a good deal.

20 **Q. Technically a failure, under the study**
21 **guidelines?**

22 A. This is a failure by their own study
23 design, set up in advance. This was a failure.

24 **Q. Did they stop or did they continue**
25 **forward?**

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1 A. They continued forward.

2 MR. SLATER: Your Honor, we're
3 done with that document.

4 THE COURT: All right. We're
5 going to take a noon break, then.

6 Justice requires that you not make up
7 your mind about this case till all the evidence
8 has been seen and heard and you must not discuss
9 the case among yourselves or with anyone else or
10 comment on anything you heard or learned in this
11 trial until the case is concluded and you retire
12 to the jury room for your deliberation.

13 Also, you must not remain in the presence
14 of anyone who is discussing the case when the
15 court is not in session.

16 Let's meet back at 1:30. Court's in
17 recess.

18 (Recess taken from 12:27 p.m. to 1:33 p.m.)

19 (The following proceedings were
20 held in the courtroom outside the presence of the
21 jury:)

22 THE COURT: Are we ready to start?

23 MR. HYDE: Yes, sir.

24 THE BAILIFF: I'll go get the
25 jurors, sir.

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1 THE COURT: Okay. If you would,
2 we'll bring the jury up.

3 Are you getting warmed up any?

4 MS. JONES: I'm not. I think it's
5 getting cooler.

6 MR. ANDERSON: I think so. It's
7 pretty cold out here, Judge. Can't feel my toes.

8 THE COURT: Well, we're turning it
9 up some, then.

10 MR. ANDERSON: Thank you.

11 THE COURT: Now, if you complain
12 that it's hot --

13 MR. ANDERSON: Well, there's a
14 happy medium. We just can't seem to find it.

15 THE COURT: We'll try to find it.
16 Okay.

17 MS. STRAUSS: Judge, I don't think
18 we've ever thought it was that hot just yet.

19 THE COURT: Not yet.

20 MS. STRAUSS: No.

21 THE COURT: I had a judge friend,
22 when the arguments would get too hot and heavy,
23 he'd turn to the bailiff and do that (indicating),
24 and I knew what he meant, and they'd run it down
25 to 55, which was the lowest denominator you could

1 have on that courthouse, and he'd just leave it
2 there until they finally froze out and he said,
3 "Well, this will end this."

4 They'd say, "Well, can we go put on a
5 coat?"

6 "No. No. You do your trial."

7 (The following proceedings were
8 held in the courtroom in the presence of the
9 jury:)

10 THE COURT: Jury's in.

11 If anybody is freezing or burning up, let
12 me know because we've had quite a discussion of
13 whether it's too cold out there or too warm up
14 here or what, so --

15 JUROR: It's really cold.

16 THE COURT: Is it pretty cold?

17 JUROR: Really cold.

18 THE COURT: Well, we turned the
19 heat up, so...

20 JUROR: Feels good in here.

21 THE BAILIFF: Your Honor, all the
22 jurors are present and accounted for.

23 THE COURT: Thank you. Be seated.

24 Ladies and gentlemen, you may be seated,
25 and Mr. Slater, you may pick up where you left

1 off, I guess.

2 MR. SLATER: Thank you very much,
3 Your Honor.

4 We call Dr. Weber back to the stand,
5 Your Honor.

6 THE COURT: And of course you
7 remember you're under the same oath you took this
8 morning.

9 THE WITNESS: Yes.

10 Q. (By Mr. Slater) Okay. Dr. Weber, in the
11 interest of time, we're going to try to move
12 things a little quicker. Okay?

13 A. Yes.

14 Q. And the first thing I'm going to ask you
15 about is: What is the Prolift IIS database?

16 Please tell the jury what those words
17 mean.

18 A. Okay. "Prolift," self-explanatory.

19 "IIS," investigator initiated study.

20 And then the database is an Excel
21 spreadsheet that has information, data collection.
22 Not the individual case report forms, but putting
23 the information from those forms into a
24 spreadsheet. So that's the database.

25 Q. And is that something that you reviewed

1 in this case?

2 A. Yes.

3 Q. And tell the jury what it is you looked
4 at.

5 A. So along with the database itself, there
6 were several other documents.

7 Dr. Lucente was the principal
8 investigator of this study, and he proposed to
9 Ethicon --

10 Which is what "investigator initiated"
11 means. So he's the investigator. He initiated
12 this study proposal to Ethicon.

13 -- and proposed to them that he report on
14 the outcomes of the patients in his clinical
15 practice. Women who had had the Prolift procedure
16 performed.

17 So I had that information, and the
18 database itself, which contained the information
19 on 514 women and follow-up -- not all of them
20 completed the follow-up and we'll see that -- more
21 about that in a little bit, but information on --
22 at baseline, before the Prolift procedure had been
23 performed, and then follow-up in different
24 intervals up to one year.

25 MR. SLATER: Let's put up the

1 first PowerPoint on this and the number of
2 patients, please.

3 MS. JONES: Could I see it,
4 please, before we put it up? Please?

5 MR. SLATER: You want to see it?

6 MS. JONES: I'd like to see what
7 you're going to put on the screen, yes.

8 MR. SLATER: I'm going to put this
9 up. She's going to see this (indicating).

10 MS. JONES: Okay.

11 **Q. (By Mr. Slater) Please tell us what this**
12 **represents.**

13 A. Okay. So this is a brief summary.

14 As I mentioned to you, it contained
15 information on 514 patients, and this represented
16 women who had had the Prolift procedure between
17 August 29th, 2005, and July 8th, 2008.

18 Out of those 514 patients, only 378 of
19 them completed follow-up at four months, which
20 means that 136 of them were lost to follow-up.
21 They didn't come back in for their appointment at
22 four months so there's no information that could
23 be collected on them at that point.

24 And then at one year, only 134 patients
25 came back for their one-year follow-up, which

1 means 380 were lost to follow-up.

2 Q. Now, you said you actually reviewed the
3 actual spreadsheets that had been documented as
4 part of this study?

5 A. Yes.

6 Q. And as part of that study, did you
7 calculate the erosion rates as documented in those
8 records?

9 A. Yes.

10 Q. Okay. And I'd like to put up a --
11 And have we prepared a PowerPoint slide
12 that actually shows what you calculated?

13 A. Yes.

14 MS. JONES: Your Honor, I --

15 THE COURT: Yes.

16 MS. JONES: I'd like to just see
17 what we're putting up before we put it up.

18 THE COURT: Yeah. Please don't
19 put anything on there you haven't shown to the
20 other side, before they get a chance to look at
21 it.

22 MS. JONES: May we approach just
23 briefly, Your Honor?

24 (Counsel approached the bench and
25 the following proceedings were held outside the

1 hearing of the jury:)

2 MR. SLATER: What's your
3 objection?

4 THE COURT: Oh, I'm sorry.

5 MS. JONES: That's all right.

6 THE COURT: Let me get this.

7 MS. JONES: Your Honor, this is an
8 analysis of Dr. Lucente's database; it's not an
9 analysis of Ethicon's database.

10 MR. SLATER: Ethicon owned the
11 data. By agreement, they owned the data --

12 (Court reporter interruption.)

13 THE COURT: I'm on? Okay. Back
14 to the drawing board.

15 MS. JONES: My objection, Your
16 Honor, is that Dr. Lucente's database is
17 Dr. Lucente's database that the plaintiff -- that
18 Ms. -- that Dr. Weber reviewed. These are not
19 Ethicon documents coming out of Ethicon's --

20 THE COURT: Business records?

21 MS. JONES: I object to that
22 basically as hearsay.

23 Now, the plaintiff is going to say -- and
24 Mr. Slater's going to say -- that under the
25 contract we had a right to look at the data, but

1 the fact is we've never seen it. It's never been
2 submitted to Ethicon. I object to it.

3 THE COURT: Now.

4 MR. SLATER: Ethicon, by
5 agreement, owned the data. They owned all the
6 rights to the data. I took his deposition by
7 court order from the New Jersey judge running
8 7,000 mesh cases. I took his deposition. He was
9 their chief consultant. He gave -- he kept the
10 data per payment. Ethicon paid for this. They
11 fund- --

12 Please let me finish.

13 MS. JONES: Go ahead.

14 MR. SLATER: Ethicon funded this.
15 They owned the data. There's nothing more
16 relevant in the world than this, and they own the
17 data, and it contradicts all of the data that he
18 ever published.

19 This is incredibly important evidence.
20 His recurrence rate is 49%. Dr. Weber calculated
21 it. They can't keep this out. They have no
22 basis.

23 MS. JONES: We have a basis to
24 keep it out that it's not Ethicon --

25 MR. SLATER: Ethicon owns it.

1 They funded the study.

2 MS. JONES: By definition, Your
3 Honor, an investigator-initiated study is one that
4 the investigator initiates, the investigator
5 conducts.

6 There is a track -- there is a contract
7 that says that Ethicon has a right to review the
8 data, but Ethicon never had this data in its
9 possession.

10 MR. SLATER: They funded the
11 study. It's one of their studies.

12 MS. JONES: It is --

13 MR. SLATER: And it's their chief
14 consultant, who was a consultant at the time,
15 Judge. He was their chief investigator for the
16 TVM study, the Gynemesh study, every single -- he
17 published data all over, he taught everybody, and
18 he told Dr. Simpson what his rates of
19 complications were. This is going to prove he
20 lied to Dr. Simpson. This is key evidence in the
21 case.

22 THE COURT: Hold it.

23 MR. BALL: Can I ask what the
24 relevance of this is because --

25 MR. SLATER: It shows that -- it

1 shows that Dr. Simpson was lied to by Ethicon when
2 she was trained on the complication rates. It
3 shows that the complication rates are far higher
4 than have ever been reported before.

5 We got -- you know what it took us to get
6 this data? We had to fight and fight. They
7 pretended it was gone. They said when an employee
8 of the place died, they couldn't find it. It took
9 us two years and the judge ordered the deposition
10 and we got it.

11 This is the death testimony in the whole
12 case.

13 MR. BALL: Your Honor --

14 MR. SLATER: I can't believe
15 they're trying to keep this out.

16 MR. BALL: -- as I understand
17 it -- and correct me if I'm wrong, Adam -- but
18 this deal with recurrence rates. Is that right?

19 MR. SLATER: And erosions. It was
20 funded by Ethicon. Ethicon --

21 THE COURT: Shhh.

22 MR. SLATER: I'm sorry. Ethicon
23 funded the study. How can they fight it? Even if
24 it was some schmoe on the street, they could -- I
25 could bring it in and then you could cross-examine

1 her on what weight to give. I don't know how you
2 can keep this out.

3 MS. JONES: You can keep it out,
4 Your Honor, because --

5 MR. SLATER: And there was no
6 in-limine motion on this either. They never filed
7 a motion on this.

8 MS. JONES: Your Honor --

9 MR. SLATER: We were supposed to
10 file motions on everything. Now they're
11 sandbagging us now in the middle of the trial as
12 if it's a new issue?

13 MR. BALL: There's no rule that we
14 have to file motions in limine on evidence.

15 MR. SLATER: Judge, I'm trying to
16 move the case along. I just cut my outline down
17 to 20 percent. I'm trying to get done by 3:30, a
18 quarter to 4:00, and I've never heard such an
19 objection. I've never heard such an objection.
20 Ethicon funded the study. They paid for it.

21 MS. JONES: Your Honor, with all
22 due respect, this is what is called an
23 investigator initiated study.

24 MR. SLATER: Which were the
25 studies they're relying on to defend the case.

1 Every one of them. The Altman study --

2 THE COURT: Go ahead and talk,
3 talk, talk, because I'm going to listen her in a
4 minute.

5 MR. SLATER: I'm sorry, Judge, but
6 every study they're relying on is an investigator
7 initiated study. The Altman study, the Withagen
8 study, they all are. But they're relying on them.
9 It's unbelievable.

10 THE COURT: What do you mean
11 they're relying on them?

12 MR. SLATER: They're using them to
13 defend the case. The same types of studies,
14 they're defending with, and now they're saying I
15 can't use it against them.

16 MS. JONES: Your Honor, this data
17 was never in Ethicon's possession. It's never
18 been published. It's --

19 MR. SLATER: It was supposed to
20 be, by contract. That's one of the points we're
21 going to make. By contract, it was supposed to be
22 and it never got published --

23 MS. JONES: Well --

24 MR. SLATER: -- because they
25 deep-sixed it.

1 MS. JONES: It's never been
2 published. The data has never been in Ethicon's
3 possession. This is hearsay. Object to it. It's
4 irrelevant.

5 And the mere fact that Dr. Lucente was a
6 consultant to Ethicon on other matters and is the
7 investigator here who never published the data and
8 let it drop doesn't mean that you can go out and
9 get all of his data and come in here and produce
10 it today.

11 MR. SLATER: I don't understand
12 that. We got a court order to get this stuff
13 against Ethicon. The judge was so angry at
14 Ethicon for hiding this that she ordered them not
15 to use J&J's same lawyers to defend Lucente for
16 this deposition. They had to get a different law
17 firm. She forbid them from using the same
18 lawyers, she was so worried, because they had been
19 hiding this from us for two years before we got
20 it.

21 MS. JONES: That is absolutely
22 false.

23 MR. SLATER: I'll produce the
24 transcripts to you.

25 MS. JONES: Well --

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1 THE COURT: No.

2 MR. SLATER: I don't need to do
3 it, Judge, but it's paid for. The study was
4 sponsored by Ethicon. They own the rights to the
5 data, Judge. I can't believe --

6 MR. BALL: The problem I see is
7 that they are trying to use data from some other
8 doctor that is all hearsay and pin it on Ethicon.
9 Okay?

10 MR. SLATER: He's the guy who
11 taught Dr. Simpson.

12 MS. JONES: But that's --

13 MR. BERGMANIS: He's the guy that
14 Ethicon paid to teach Dr. Simpson.

15 MR. SLATER: They paid him to
16 teach Dr. Simpson about the complication rates.

17 MR. BALL: The study -- this
18 study, you can tell by the data that it didn't
19 even get -- the last piece wasn't even in until
20 after her surgery, so it doesn't have anything to
21 do with --

22 MR. SLATER: Dan, you're using --
23 all your studies post-date the plaintiff's
24 surgery. They are all from 2011.

25 MR. BALL: I was responding to

1 your argument that Dr. Lucente taught Dr. Simpson,
2 because he didn't teach her about this study
3 because the surgery was long gone by then.

4 MR. BERGMANIS: But he had the
5 data.

6 MR. SLATER: He had the data.

7 MR. BERGMANIS: He had the data
8 and he didn't tell Dr. Simpson. He lied to
9 Dr. Simpson.

10 MR. SLATER: This is punitive
11 damage evidence.

12 MS. STRAUSS: Your Honor --

13 THE COURT: Is there evidence of
14 that?

15 (Court reporter interruption.)

16 THE COURT: I'm sorry.

17 MR. SLATER: Yes. We're about to
18 give it to you.

19 MR. BALL: There's no evidence --

20 THE COURT: No. You're about to
21 put that up, is what you're about to do.

22 MR. BALL: There's no evidence in
23 this case about when Dr. Simpson and Dr. Lucente
24 interacted in relation to this data. There's no
25 evidence in this case to that effect.

1 They put her on for two or three hours

2 and no -- not one iota of evidence --

3 (Court reporter interruption.)

4 THE COURT: Just a minute.

5 MR. BALL: You don't have that --

6 MR. SLATER: I do.

7 THE COURT: He can't -- you're not

8 making --

9 MR. SLATER: I do. I have the
10 internal documents.

11 MR. BERGMANIS: Just stop for a
12 second.

13 THE COURT: You're not going to
14 have a record on that if we don't slow down.

15 MR. SLATER: Mr. Ball doesn't
16 realize we have documentation that if the
17 Prolift --

18 THE COURT: Well, I'll tell you
19 what, you come back to it later and I'll consider
20 it. It's out right now.

21 MR. SLATER: Judge, she's the only
22 witness I have on it.

23 THE COURT: Step back.

24 (The proceedings returned to open
25 court.)

1 THE COURT: Proceed.

2 Q. (By Mr. Slater) Take the PowerPoint
3 down.

4 Dr. Weber, I've handed you a document
5 marked Plaintiff's Trial Exhibit 1557. Have you
6 seen this document before?

7 A. Yes, I have.

8 Q. Is this a document you rely on for your
9 opinions in this case?

10 A. Yes.

11 Q. Please put this document up.

12 In the fourth line, let's highlight where
13 it points out that there are patients post-Prolift
14 who cannot void.

15 What does that mean?

16 A. So that means they can't empty their
17 bladders. They have the -- their bladder fills
18 normally. You know, the kidneys are always
19 putting out urine and the bladder fills, but
20 they're just not able to release that.

21 Q. And if we go a little further down, to
22 the sentence that starts six lines up with the
23 word "but," can you highlight that, please?

24 And it says, "But if this starts getting
25 reported, it is going to scare the daylights out

1 of doctors."

2 And this was in October of 2005, correct?

3 A. Yes.

4 Q. Did they -- did Ethicon ever publicize
5 that they had patients who had this complication
6 where they couldn't even urinate and clear urinary
7 retention?

8 A. No.

9 Q. Do you have an opinion as to whether or
10 not Ethicon failed to adequately warn with regard
11 to this complication?

12 A. Yes, I do have an opinion.

13 Q. What is that?

14 A. My opinion is that they failed to warn at
15 all as to the -- this kind of a complication:
16 inability to void for a prolonged period of
17 time.

18 MR. SLATER: Actually, Your Honor,
19 maybe -- can I try to lay a foundation for what we
20 discussed up at sidebar a few moments ago?

21 THE COURT: No. Let's go on with
22 something else.

23 Okay. Go ahead.

24 MR. SLATER: Thank you.

25 THE COURT: Lay your foundation

1 and then I'll rule on it again.

2 MR. SLATER: Thank you.

3 Q. (By Mr. Slater) I want to come back --
4 we can take that document down.

5 Dr. Weber, have you read all of the
6 documents that were produced by Dr. Lucente with
7 regard to his IIS database?

8 A. Yes.

9 Q. Have you read his sworn deposition and
10 that of his partner, Miles Murphy, regarding that
11 database?

12 A. Yes, I have.

13 Q. Have you read the agreement between
14 Ethicon and Dr. Lucente for this database?

15 A. Yes, I have.

16 Q. Can you tell the jury the important
17 points of that agreement?

18 MS. JONES: Objection, Your Honor.

19 THE COURT: If it's between that
20 doctor and --

21 MS. JONES: Ethicon.

22 THE COURT: -- who was the other
23 party?

24 MR. SLATER: Ethicon. Ethicon.

25 It's -- Dr. Lucente had a contract with Ethicon.

1 MR. BERGMANIS: It's part of the
2 foundation, Your Honor.

3 MR. BALL: I think the agreement
4 speaks for itself.

5 THE COURT: Well --

6 MR. BERGMANIS: It's part of the
7 foundation.

8 MR. SLATER: Can my expert
9 describe what it said and then she can explain --

10 THE COURT: Do we have a copy of
11 it?

12 MR. SLATER: I don't have it in
13 the room. I can have it printed in the next 10
14 minutes.

15 THE COURT: All right. Go ahead
16 and ask questions, but I'd like to see a copy of
17 it.

18 Q. (By Mr. Slater) Tell the jury the
19 important points of the agreement, please.

20 A. Okay. So this consulting agreement
21 between Ethicon and Dr. Lucente stipulated that --
22 stipulated requirements in completing the study,
23 and one of the requirements was that Dr. Lucente
24 publish his results. That makes sense. If he's
25 going to do the study, then the results should

1 become known to the scientific community.

2 And it is standard for an Ethicon
3 contract of this type. Ethicon owned the data
4 themselves. Dr. Lucente was required to provide a
5 report to Ethicon.

6 MS. JONES: Objection, Your Honor.
7 I don't believe Dr. Weber is qualified to testify
8 to the legal ramifications of that contract.

9 MR. SLATER: She's explaining the
10 terms of the contract. She's an expert, and
11 certainly an expert with regard to clinical
12 studies.

13 MS. JONES: Your Honor, the issue
14 is the contract of an independent --

15 THE COURT: I'd like -- let's just
16 stop that. I want to see that contract before we
17 go any further.

18 MR. SLATER: Fair enough. I'll
19 move on and we'll come back.

20 THE COURT: All right. Doctor,
21 we're going to go to another subject. I'm not
22 taking that up right now.

23 MR. SLATER: Okay.

24 THE COURT: Are you an attorney at
25 law? Are you an attorney at law?

1 THE WITNESS: No, I am not.

2 THE COURT: Have you gone to law
3 school?

4 THE WITNESS: No, I have not.

5 THE COURT: All right, all right.

6 Q. (By Mr. Slater) Are you --

7 THE COURT: We'll take that
8 up later.

9 Q. (By Mr. Slater) Are you an expert with
10 regard to clinical study agreements?

11 A. Yes, I am.

12 Q. Did you run the program at the NIH
13 whereby \$50 million was being used to fund
14 research all over the United States?

15 A. Yes, I was.

16 Q. And did you have the supervisory
17 authority over that contracting?

18 A. Yes, I did.

19 THE COURT: Well, one question
20 there. Did you draw the agreements or did your
21 legal department draw them?

22 Did you draw the agreements yourselves or
23 did your legal departments at the National
24 Institute of Health --

25 THE WITNESS: No.

1 THE COURT: -- take care of those?

2 THE WITNESS: I drew those
3 agreements myself.

4 THE COURT: You did?

5 THE WITNESS: Yes, I did.

6 THE COURT: Put in all the
7 ramifications and terminology?

8 THE WITNESS: Yes.

9 THE COURT: All right.

10 Q. (By Mr. Slater) I've handed you a
11 document marked as Exhibit 1238. Have you seen
12 this document before?

13 A. Yes, I have.

14 Q. Is this a document on which you rely on,
15 in part, for your opinions in this case?

16 A. Yes.

17 Q. Let's put this up, Exhibit 1238.

18 MS. JONES: Your Honor, I object.

19 THE COURT: Which one is it? I --

20 MS. JONES: I object to this --

21 THE COURT: I haven't seen it.

22 MS. JONES: -- because this refers
23 to a matter that I think Your Honor said you would
24 take up later on. I think --

25 THE COURT: If that's part of

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1 that, I thought we --

2 MS. STRAUSS: No, no. It's not.

3 MS. JONES: It's not. I don't
4 mean to mislead the court. It's not part of that
5 subject.

6 THE COURT: Okay.

7 MS. JONES: But it does deal with
8 a patient other than Ms. Budke.

9 MR. SLATER: It's a report of an
10 adverse event very similar to hers to the
11 company --

12 MS. JONES: No.

13 MR. SLATER: -- three years
14 before.

15 THE COURT: No, no, no. Come on
16 up here.

17 MR. SLATER: Oh, my God.

18 THE COURT: We're not getting
19 anywhere here.

20 (Counsel approached the bench and
21 the following proceedings were held outside the
22 hearing of the jury:)

23 MR. BALL: Your Honor, our
24 objection is that this is in reference to an event
25 other than Ms. Budke's.

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1 THE COURT: That's what I was
2 trying to get.

3 MR. BALL: It's hearsay --

4 THE COURT: Yes, it is.

5 MR. BALL: -- it's hearsay and
6 it's without proper foundation and you cannot put
7 in other individual events of other people, other
8 lawsuits, other people. You can't do it. You can
9 talk statistically, but you can't put in specific
10 other events without -- because they're all
11 hearsay, and unless somebody comes in with
12 firsthand knowledge of the event and establishes
13 that the event is very similar to Mrs. Budke's
14 event, you can't put it in. And you can't put it
15 in through a piece of paper; it has to be a person
16 with firsthand knowledge. That's black letter
17 law.

18 MR. BERGMANIS: Black letter law
19 is experts always rely on hearsay.

20 MR. SLATER: I'm sorry, but this
21 isn't hearsay.

22 THE COURT: I didn't hear you.

23 MR. BERGMANIS: Oh. Black letter
24 law is that --

25 MR. SLATER: I'm sorry, Judge.

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1 MR. BERGMANIS: -- experts always
2 rely on hearsay.

3 MR. SLATER: This is a business
4 record written by Ethicon.

5 MS. JONES: In response --

6 MR. BALL: It doesn't matter --

7 MR. SLATER: Please let me finish.
8 You guys are crushing me, so just let me talk.
9 I'm -- you know.

10 THE COURT: I'll let you talk.
11 Talk, talk, talk, talk. I will. But damn it, you
12 can't -- it's either --

13 MR. SLATER: Judge, you've already
14 ruled this in evidence. You ruled in our favor.
15 You said if it predates it and it's very
16 similar --

17 This is -- this is vaginal erosion.

18 THE COURT: "Dear redacted." I'm
19 telling you that is hearsay.

20 MR. SLATER: Judge, it's a letter
21 written by the company. It's their official
22 business record about an adverse event report.

23 If this goes out, I can't use one piece
24 of paper in this case.

25 MR. BALL: Oh.

1 MS. JONES: Your Honor --

2 MR. BALL: You --

3 MR. SLATER: And now that we -- he
4 just made an argument that all I can put in is
5 statistical analyses?

6 To say that, I have adverse event reports
7 to the company predating her surgery giving them
8 notice of the defect. I have negligence claims.
9 They ignored this. I have all sorts of claims.
10 This is implicated by punitive damage claims in
11 this case. They're ignoring all this.

12 MR. BALL: Then he should have
13 gotten the right foundation, and the right
14 foundation is not to come up with an out-of-court
15 statement, a piece of paper, and try and show
16 other --

17 MR. SLATER: It's a business
18 record of the company.

19 MR. BALL: It is not because it
20 contains hearsay in it about the report of the
21 event.

22 MR. SLATER: Oh, my gosh, it's --

23 MR. BALL: I deal with this every
24 time in a product liability case where they try to
25 put into evidence other events that have happened

1 to people besides this. There's a very specific
2 way that they can try to do this and they haven't
3 done it and they can't do it in this case.

4 We have to have somebody with firsthand
5 knowledge who can establish that the other event
6 is substantially similar to Mrs. Budke's.

7 MS. JONES: Your Honor, this
8 letter, Exhibit 1238, is a response from the
9 company to a doctor --

10 THE COURT: Presumably.

11 MS. JONES: -- in response to an
12 adverse reaction report that's not been
13 demonstrated to be similar to Ms. --

14 MR. SLATER: We have a failure
15 to --

16 THE COURT: Go ahead. What?

17 MS. JONES: It's dissimilar, it
18 contains hearsay, and therefore is irrelevant to
19 this claim.

20 MR. SLATER: Judge, I have a
21 failure to warn claim. Their knowledge of the
22 risks is my basis for what they're supposed to
23 warn of. This is their knowledge base. This is
24 their business records.

25 THE COURT: I thought you were

1 doing a pretty good job of getting that point
2 across.

3 MR. BALL: He's already provided
4 all kinds of testimony about --

5 MR. SLATER: Are you stipulating
6 to liability?

7 MR. BALL: No.

8 THE COURT: No --

9 MR. BALL: I suspect --

10 THE COURT: -- they're not doing
11 that.

12 MR. SLATER: Then you know what,
13 Judge?

14 THE COURT: They don't want to
15 sound that dumb to the Court.

16 MR. BALL: You've put in -- you've
17 put -- he's put in multiple pieces of testimony
18 about what was supposedly known to Ethicon
19 beforehand. This is a step farther where he's
20 trying to show, through hearsay evidence, other
21 events other than Mrs. Budke. He can't do that.
22 I can't help --

23 MR. SLATER: So I'm limited only
24 to Mrs. Budke's situation to prove my case? Come
25 on.

1 MR. BALL: You are not allowed --

2 MR. SLATER: Stop.

3 MR. BALL: This is standard. You
4 are not allowed to put in other events and
5 incidents involving people with a product without
6 a sufficient foundation, and that isn't enough
7 foundation. It's not even --

8 MR. SLATER: It's their business
9 record. Let them bring someone in --

10 MR. BALL: It's hearsay --

11 MR. BERGMANIS: Hold on, hold on.

12 MR. SLATER: It didn't really
13 happen --

14 MR. BERGMANIS: This will take
15 care of it. Amy's got the hearsay issue.

16 MS. GUNN: Your Honor, I have
17 tried to listen. I have a case -- I have a case
18 that's Patterson. Your Honor, there is no
19 question -- there is no question that experts can
20 rely on hearsay. Experts can rely on hearsay.
21 They can take anything and rely on it. Otherwise,
22 they wouldn't be able to have anything other than
23 their firsthand knowledge.

24 It's clear in Missouri that experts can
25 rely on hearsay. So any objection based on

1 hearsay is entirely unfounded.

2 MR. BALL: That is not -- that is
3 not part of the basis --

4 MR. BERGMANIS: Black letter law.

5 MR. BALL: That is not the basis
6 of the objection, Your Honor.

7 Just so we're clear, the objection is not
8 that an expert can't rely on hearsay. That is not
9 the objection.

10 The objection is that you cannot put in
11 front of the jury another incident involving
12 another person. You can't put that in whether
13 it's an expert or not an expert. You can't put
14 another person's event in front of the jury unless
15 you have a firsthand-knowledge foundation that
16 establishes substantial similarity.

17 Taking a case and saying that an expert
18 can rely on a policeman's diagram has nothing to
19 do with this incident.

20 MS. GUNN: It has --

21 MR. BALL: Nothing.

22 MS. GUNN: -- everything. It's
23 exactly the same.

24 MR. BERGMANIS: You just -- you
25 just said it was hearsay a minute now. Now you're

1 saying it's not a hearsay objection?

2 MR. BALL: It is hearsay but it's
3 as -- it's hearsay in another -- another event
4 objection. I've said that repeatedly.

5 MR. BERGMANIS: It goes to weight.
6 You get to cross-examine.

7 MS. GUNN: It goes to the weight,
8 not the admissibility of it. We're trying to
9 establish the basis of her opinions.

10 MR. BALL: Your Honor, you
11 already ruled on this.

12 THE COURT: Yeah. I think this is
13 trying to be -- independent substantive
14 evidence --

15 MS. JONES: Your Honor --

16 (Court reporter interruption.)

17 THE COURT: Okay. Here's what I'm
18 going to do.

19 I'm good to sustain the objection on the
20 ground that this letter is not offered as
21 independent substantive evidence.

22 MR. BALL: Right.

23 THE COURT: It's just a -- another
24 person that wrote the company about something.

25 MR. SLATER: Judge, it's the

1 company --

2 THE COURT: Shhh.

3 MR. BERGMANIS: Can you do it
4 through notice?

5 MR. SLATER: -- sponsoring and
6 considering it.

7 MR. BALL: You already ruled on
8 this.

9 MR. SLATER: They have systems
10 when they --

11 THE COURT: Take me up on it.

12 (The proceedings returned to open
13 court.)

14 Q. (By Mr. Slater) Dr. Weber, I've handed
15 you a medical article with the stamp PLT0108. Are
16 you familiar with this article?

17 A. Yes, I am.

18 Q. Is this an article that you believe to be
19 authoritative with regard to the subject matter it
20 addresses in this field?

21 A. Yes.

22 Q. Who are the authors of this article?

23 A. The authors are part of the French TVM
24 group, the transvaginal mesh group that worked on
25 developing the procedure.

1 Q. And who's the last named author?

2 A. Michel Cosson.

3 Q. And what's the significance of who is
4 listed as the last author in the string?

5 A. That's typically the senior author.

6 Q. And this is dated as having been received
7 by this journal, the International Urogynecology
8 Journal --

9 A. Yes.

10 Q. -- March 22, 2005, and was accepted for
11 publication July 25, 2005, is that correct?

12 A. Yes.

13 Q. First, just in the abstract in the
14 beginning, what was -- what was the number of
15 patients studied, what was being studied, first of
16 all?

17 A. Okay. So they studied 277 patients who
18 were undergoing surgery with the transvaginal mesh
19 implantation technique, and they wanted to learn
20 how many women developed a mesh erosion.

21 Q. And what was their stated rate?

22 A. That was 34 cases within two months of
23 surgery at 12.27%.

24 Q. And do you have an opinion, to a
25 reasonable degree of medical certainty, as to

1 **whether that shows this to be a safe or unsafe**
2 **device?**

3 A. Yes.

4 **Q. And what's your opinion?**

5 A. My opinion is that this is unsafe.

6 **Q. Now, have you read the conclusion by the**
7 **authors of this article?**

8 A. Yes, I have.

9 **Q. And what was their conclusion?**

10 A. Their conclusion was that a mesh erosion
11 rate of 12.27% at only two months of follow-up was
12 too high to be acceptable, and they felt like the
13 technique was still experimental unless they were
14 able to -- until they were able to bring the mesh
15 erosion rate below 5%.

16 **Q. And this was in 2005?**

17 A. Yes.

18 **Q. And was the Prolift on the market at this**
19 **point?**

20 A. It was just, yes. For a few months.

21 **Q. And when someone says a -- something**
22 **should be experimental, what does that mean?**

23 A. That means that there's not enough
24 evidence to weigh in the risk balance -- excuse
25 me, risk/benefit equation.

1 For example, in a doctor talking with a
2 patient in terms of undergoing a procedure like
3 the Prolift procedure, there isn't enough
4 information to say, "In your case, the risks are
5 going to be outweighed by the benefits and
6 therefore I recommend you go ahead."

7 So when it's experimental, there isn't
8 enough information of that sort and the doctor
9 isn't able to say whether the risks outweigh the
10 benefits, and if the woman chooses to undergo that
11 procedure, she understands that this is an
12 experiment and she enters into that voluntarily:

13 **Q. If something's experimental, would it be**
14 **sold widespread on the market, as the Prolift was?**

15 MS. JONES: Objection, Your Honor.
16 I think this --

17 MR. SLATER: I'm asking for
18 definition of terminology, Your Honor.

19 THE COURT: What are we talking
20 about?

21 MR. SLATER: Talking about whether
22 or not something that's experimental should be
23 sold on the market for widespread use.

24 I'm asking Dr. Weber as an expert to
25 answer that question.

1 MS. JONES: And I think that's
2 beyond her qualifications.

3 Q. (By Mr. Slater) Are you an expert with
4 regard to the implications of something being
5 deemed experimental in the field of medicine?

6 A. Yes, I am.

7 Q. Is that something that you actually
8 considered on a day-to-day basis in your academic
9 and research work?

10 A. Yes.

11 Q. Would you please tell us: Would an
12 experimental product be sold for widespread
13 marketing?

14 MS. JONES: Objection, Your Honor.

15 THE COURT: Well, you can answer
16 the question.

17 THE WITNESS: Thank you.

18 A. No.

19 Q. (By Mr. Slater) Why not?

20 A. By its very definition, experimental
21 means it should be used in a trial setting, in a
22 research setting, where the woman understands and
23 participates voluntarily, consents to participate
24 in an experiment, not something that's in
25 widespread use, in clinical use, where women don't

1 understand that it's experimental.

2 Q. Okay. Doctor, I've handed you what we've
3 marked as PLT0139A.

4 THE COURT: What was that number?
5 Zero --

6 MR. SLATER: 0139A.

7 THE COURT: All right.

8 Q. (By Mr. Slater) Is this a medical
9 article that you're familiar with?

10 A. Yes.

11 Q. And is this something you consider to be
12 authoritative in this field?

13 A. Yes.

14 Q. Okay. Doctor, will you tell the jury
15 what this is.

16 A. Okay. So this is a research article
17 that's presenting a summary of the use of
18 synthetic mesh for prolapse repair.

19 Q. And who are the authors? Who are the
20 people that are talking about the use of this
21 mesh?

22 A. These are also members of the French
23 transvaginal mesh group.

24 Q. Including Dr. Cosson?

25 A. Yes.

1 Q. Okay. What I'd like to do now is I'd
2 like to ask you --

3 First of all, I'm going to read a --

4 Well, let me just ask you this: Did they
5 comment upon the use of Prolene Soft mesh, the
6 mesh they had been using and at this time was on
7 the market in the Prolift?

8 A. Yes.

9 Q. And what is it that they said about that?

10 MS. JONES: Objection, Your Honor.

11 This --

12 MR. SLATER: I'll rephrase the
13 question.

14 THE COURT: All right.

15 Q. (By Mr. Slater) Based on this article,
16 what is your understanding as to what the position
17 was as to the authors of this article, including
18 Cosson?

19 MS. JONES: Same objection.

20 Hearsay.

21 THE COURT: Well, fair enough.

22 She can answer it.

23 A. Okay. The authors concluded that the
24 Gynemesh PS mesh in the Prolift did not fulfill
25 expectations.

1 **Q. (By Mr. Slater) Do you have an**
2 **understanding from this article about whether or**
3 **not from their work here they felt that it was**
4 **appropriate to have the widespread use of**
5 **synthetic mesh for the treatment of prolapse?**

6 A. No.

7 MS. JONES: Objection.

8 A. I mean, I'm sorry, I do have an opinion.

9 **Q. (By Mr. Slater) And what is that?**

10 A. The opinion is no.

11 **Q. And explain that.**

12 A. They felt like the --

13 MS. JONES: Objection, Your Honor.
14 I believe that's hearsay. I don't believe she can
15 testify --

16 THE COURT: I'm sorry?

17 MS. JONES: It's hearsay.

18 THE COURT: Well, I think that the
19 thing speaks for itself. She can read what they
20 said but I won't let her put her innuendo on it,
21 if you've got it there.

22 **Q. (By Mr. Slater) And what did they say**
23 **with regard to that issue?**

24 A. Okay. They said the Prolift kit -- the
25 follow-up on patients with the Prolift kit was

1 still too short for proper assessment.

2 This is after the Prolift is on the
3 market in the United States.

4 Q. And what did they say starting with
5 "proposed to improve these phenomenon," right
6 under that black line in the middle?

7 MR. BALL: Your Honor, Your
8 Honor --

9 THE COURT: Yes.

10 MR. BALL: -- they are not
11 entitled to read the -- they are not entitled to
12 read from a document like this. This is hearsay.
13 She can say she can have an opinion, she can say
14 this expresses the opinion, but they can't read
15 from it or paraphrase it. It's hearsay.

16 THE COURT: All right. Ask her a
17 question, then, and she can give us what her
18 opinion is on it.

19 Q. (By Mr. Slater) What is your opinion as
20 to whether or not they had reservations about the
21 widespread use of synthetic meshes?

22 MR. BALL: That's the same thing.
23 He's asking her hearsay. He can ask her opinion
24 about whether mesh -- she's already said four
25 times what her opinion is about mesh. She can say

1 this supports it but she can't read the document.

2 It's a hearsay --

3 MR. SLATER: I wasn't asking her
4 to, sir. I asked her what his understanding was
5 as to a question that I asked her. I didn't ask
6 her to read the documents.

7 MR. BALL: He asked about what was
8 your understanding of what they said. That is
9 hearsay and he -- he's trying to --

10 Q. (By Mr. Slater) What is your
11 understanding as to whether or not they thought
12 that the Gynemesh --

13 THE COURT: Drop the "they
14 thought."

15 MR. SLATER: I don't know --

16 THE COURT: I mean, I assume that
17 when a doctor reads this type stuff, they read it
18 with their understanding of what it is, and so...

19 Q. (By Mr. Slater) Is it -- as a doctor in
20 the field, when you read an article like this,
21 based on who these people were and their role in
22 the development of the Prolift procedure, would it
23 be of interest to understand what they thought,
24 based on their study?

25 A. Yes.

1 Q. Would that be standard within the medical
2 community?

3 A. Yes.

4 Q. And is that how you've read this and
5 understood it?

6 A. Yes.

7 Q. And is it important to you in forming
8 your opinions?

9 A. Yes.

10 Q. What is your understanding as to whether
11 or not the inventors of the Prolift were
12 comfortable with the widespread use of synthetic
13 meshes, after all their work with the Prolift?

14 MR. BALL: Objection as hearsay,
15 Your Honor. It's -- he's asking the same thing
16 four different ways. It's all hearsay.

17 THE COURT: I'm -- I'm going to
18 allow it one time if you just won't beat it to
19 death. Okay?

20 MR. SLATER: Thank you.

21 A. Okay. The inventors were not comfortable
22 with having the procedure used widespread in
23 clinical practice.

24 As we've mentioned, they felt that the
25 erosion rate was too high, that it needed to be at

1 least under 5%, and they weren't anywhere close to
2 that.

3 Q. (By Mr. Slater) Dr. Weber, we've spoken
4 about the ACOG practice bulletin that you authored
5 earlier in your testimony. Remember that?

6 A. Yes.

7 Q. And what I'm going to do now is ask you:
8 Factually, what happened to that practice bulletin
9 after you authored it and it was published? What
10 factually occurred?

11 A. What occurred is that a small number of
12 clinicians contacted the American College of
13 Obstetrics and Gyn- -- Obstetricians and
14 Gynecologists to express their reservations over
15 the term "experimental" because they were worried
16 this meant insurance companies would not pay for
17 the procedure, since they don't typically pay for
18 things that are experimental, and they were also
19 concerned that this would increase their
20 medical-legal risk if a patient of theirs
21 experienced a complication in the setting of a
22 procedure that was deemed experimental.

23 Q. I'm going to show you a document that has
24 been received -- the jury's seen this document and
25 it's been testified to -- and I want to ask you

1 from your viewpoint as the author of the study:

2 When did you learn about Ethicon's direct
3 involvement in this process?

4 MS. JONES: Objection, Your Honor.
5 Assumes facts not in evidence.

6 MR. SLATER: I'll ask it
7 differently.

8 THE COURT: All right.

9 Q. (By Mr. Slater) We've handed you Exhibit
10 P2299. Is this an email chain you've seen?

11 A. Yes.

12 Q. And is this significant to you, as the
13 author of the article?

14 A. Yes.

15 Q. Why?

16 A. Because before I saw this document, I
17 didn't realize that Ethicon and its paid
18 consultants were working --

19 MS. JONES: Objection, Your Honor.

20 A. -- to --

21 THE COURT: Just a minute.

22 MS. JONES: Excuse me, Your Honor.

23 The document speaks for itself. It's
24 cumulative, there's been testimony about it, and
25 the doctor -- the jury can decide what it means.

1 THE COURT: Well, it's been
2 published so it's going to go back to them.

3 MS. JONES: It's not the subject
4 of appropriate expert testimony or of Dr. Weber --

5 MR. SLATER: She's also testifying
6 factually, Your Honor. She's the person who wrote
7 it. Who could better talk about it than her?

8 THE COURT: Wrote this right here
9 (indicating)?

10 MR. BALL: She didn't write this.

11 MR. SLATER: No. She wrote the
12 article.

13 THE COURT: Well, then they can
14 interpret that. They're the trier of facts. It's
15 going to go back to them, unless you tell me you
16 don't want it to go back.

17 Q. (By Mr. Slater) Without stating --

18 THE COURT: If nothing else, it
19 invades the province of the jury.

20 Q. (By Mr. Slater) I'm sorry.

21 Without stating what was in the email,
22 what was your reaction when you read the emails?

23 MS. JONES: Objection, Your Honor.
24 That's irrelevant.

25 THE COURT: Well, that's her state

1 of mind. I don't...

2 MR. SLATER: Okay.

3 THE COURT: She can testify to
4 medical opinions, but not state of mind.

5 Q. (By Mr. Slater) We've just handed you,
6 Dr. Weber, PLT0506. What is this?

7 A. This is a letter to the editor that I
8 wrote to describe the situation that occurred
9 between the publication of the original practice
10 bulletin and the retraction and publication of a
11 second bulletin.

12 Q. And why did you write this letter?

13 A. I wrote this letter because I was very
14 concerned that my professional organization, the
15 American College of Obstetricians and
16 Gynecologists, was taking a stand that instead of
17 advocating for women's safety actually endangered
18 their safety.

19 I thought that was an inappropriate
20 response, and it was very concerning to me that
21 other doctors need to know about this to
22 understand what had happened between the initial
23 publication --

24 THE COURT: Okay. Just -- have
25 you got an objection?

1 MS. JONES: I do have an objection
2 at this stage, Your Honor. I think it's
3 irrelevant and beyond the scope of the question.

4 THE COURT: Let's play Q&A if we
5 can.

6 MR. SLATER: Your Honor, I'm
7 asking why she wrote the letter that I'm about to
8 ask her to read to the jury so they can know what
9 position she took so they can understand the
10 letter --

11 THE COURT: Is that in evidence?

12 MS. JONES: No.

13 MR. SLATER: Well, it's being used
14 with the witness who wrote it for the first time
15 in the case right now.

16 THE COURT: It's never been
17 published before?

18 MR. SLATER: It has not, but the
19 author of it is here now.

20 THE COURT: All right. Okay.

21 Q. (By Mr. Slater) So --

22 MR. BALL: Your Honor --

23 THE COURT: Yes.

24 MR. BALL: -- I would object to
25 the relevance of this. This is a -- this is a

1 dispute between this witness and the American
2 College of Obstetricians and Gynecologists that is
3 not relevant to this case.

4 This case is about whether the Prolift
5 benefits outweighed the risks, and that's
6 what it's-- all it's about, and whether they had
7 had some kind of dispute going on is collateral
8 and irrelevant.

9 MR. SLATER: Your Honor, it's
10 relevant for many reasons. I'd rather not -- I
11 thought we were supposed to do it at sidebar but
12 it's relevant for many reasons.

13 THE COURT: Let's just don't have
14 her read it. If she was involved in it, she knows
15 what it says. She's an intelligent woman.

16 MR. SLATER: Your Honor, the jury
17 needs to hear this.

18 THE COURT: Are you not going to
19 ask to have it admitted into evidence?

20 MR. SLATER: Of course I'm going
21 to ask to have it admitted into evidence.

22 THE COURT: Well, then they're
23 going to have an opportunity to read it.

24 MR. SLATER: Shouldn't they have
25 the opportunity for us to put it in the record at

1 the trial?

2 This is important evidence in our case,
3 Your Honor.

4 MR. BALL: Our objection stands,
5 Your Honor. Our objection stands.

6 MR. SLATER: She's the author of
7 the letter.

8 MR. BALL: Doesn't matter.

9 MR. BERGMANIS: Your Honor, it --

10 MS. JONES: It's irrelevant to the
11 issues in this case, Your Honor.

12 MR. BERGMANIS: It's going to go
13 into evidence and they're going to get a whole
14 pile of --

15 THE COURT: I just got -- did I
16 not say that?

17 MR. BERGMANIS: I was just going
18 to ask that we put it up on the screen, because
19 otherwise they're going to get this whole pile and
20 we may as well do it in context.

21 MR. BALL: This is getting --

22 MR. BERGMANIS: They're going to
23 have stacks of documents back there anyway, and if
24 they're going to see it anyway --

25 THE COURT: Well, let's -- I'm not

1 going to publish it out here and then send it back
2 with them. If he wants to ask her some questions
3 about it, that's fine, but you can send that back.
4 It becomes part of the record if I admit it. You
5 know that.

6 MR. SLATER: I know that, Your
7 Honor, but I think that at a trial we need to let
8 the jury hear the evidence in the flow of the
9 trial as we deem fit.

10 MR. BALL: I'm not going to repeat
11 my objection, Your Honor.

12 THE COURT: Well, I'm going to let
13 you ask questions about it. I'm not going to let
14 you have her read it into evidence, if it's going
15 to be there otherwise.

16 So if you want to ask her some questions
17 about it, let's do it. If you don't, let's put it
18 down and go to something else.

19 MR. SLATER: All right, Your
20 Honor. Then I guess I'll ask her to interpret it
21 as I go. I don't know any other way to do it.

22 THE COURT: Mighty fine.

23 Q. (By Mr. Slater) Okay. Dr. Weber, this
24 was written August 8, 2009. That was when it was
25 actually submitted to the International

1 Urogynecology Journal?

2 A. Yes.

3 Q. Now, when you took the positions that you
4 took in this letter, had you ever spoken with me?

5 A. No.

6 Q. So this shows what your opinions and
7 viewpoints were before you ever became involved in
8 this litigation?

9 A. Yes.

10 Q. And in the first paragraph --

11 I'll go to the second paragraph, and it
12 says that after you had learned what happened, you
13 said, "The explanation I was given at the time why
14 ACOG decided to change the wording, over my
15 strenuous objection, was that the meaning of the
16 word 'experimental' was ambiguous. This is
17 disingenuous at best. In fact, the ACOG staff
18 member at the meeting of the committee on practice
19 bulletins, gynecology, described the real reason
20 for concern, quote, recognition that the current
21 wording would possibly deny payment for some
22 physicians."

23 Now I want to stop there.

24 When you wrote this letter, did you have
25 any concerns about putting this out there for

1 every doctor not only in the United States but
2 abroad to see your viewpoints, or did you want
3 them to see what you had to say?

4 A. No, I wanted to -- I wanted to tell the
5 story of what happened.

6 Q. You say -- I'm going to ask you what this
7 means.

8 MR. BALL: Your Honor, he's
9 continuing to just read from the letter --

10 THE COURT: Well, here's what --

11 MR. BALL: -- and ask her why she
12 did -- why she had this dispute with the American
13 College. That is a completely irrelevant matter.

14 THE COURT: It's already -- this
15 has already been bordered way on once before. I
16 recall that. Where you talked about these very
17 things. And you would like, of course, to
18 reinforce it with the author of it, or whatever,
19 but I mean --

20 MR. SLATER: We're trying to prove
21 that this procedure should have always been
22 experimental and never should have been on the
23 market. We got the author of the thing telling
24 the jury why that word "experimental" belonged in
25 there, Judge.

1 THE COURT: I thought you'd
2 already -- I thought we did that before, and as to
3 why they took it out was because of things
4 unrelated.

5 MR. SLATER: Judge, there's more
6 to this story and I have a right --

7 THE COURT: Oh, man, I know it.
8 There's probably six weeks of it, but let's --
9 okay. Just go ahead and do it because I want to
10 get -- get done --

11 MR. SLATER: I'm trying and I get
12 an objection every time I open my mouth.

13 THE COURT: I know you do. Okay.
14 Can you do something besides just read it to her?

15 MR. SLATER: Well, I'd prefer --
16 that was your question, Judge.

17 THE COURT: Go right -- go
18 right -- go right ahead. Be my guest. We got all
19 kinds of time.

20 Q. (By Mr. Slater) You wrote: "Most of the
21 clinicians who objected to the use of the word
22 'experimental' understood only too well exactly
23 what meaning was intended, that the use of mesh
24 kits as procedures for prolapse lacked sufficient
25 evidence of risk versus benefit to adequately

1 counsel patients as to expected outcomes. Such
2 clinicians were concerned that insurance companies
3 would not cover procedures labeled experimental
4 and they were concerned about the medical-legal
5 risks, should a complication arise in the course
6 of procedures labeled experimental."

7 That's what you've explained to the jury?

8 A. Yes.

9 Q. And you took that position back in August
10 of 2009?

11 A. Yes.

12 Q. And is that the position you take today
13 as you stand before this jury?

14 A. Yes.

15 Q. And you say, "Exactly the kinds of
16 concerns that a professional organization that
17 truly promoted best medical practices would see as
18 a red flag that clinicians' concerns were not
19 focused on what was best for the patient but on
20 what protected their income. That ACOG chose to
21 align itself with these few fellows at the expense
22 of patients' outcomes and safety is of grave
23 concern."

24 Do you still hold these opinions today?

25 MR. BALL: Same objection, Your

1 Honor, about hearsay and irrelevance.

2 MR. SLATER: It's hearsay? She's
3 the author of it, sir.

4 THE COURT: I -- go ahead. I'll
5 overrule it. Go ahead.

6 Q. (By Mr. Slater) And you said, "If ACOG
7 had actually decided that the meaning of the word
8 'experimental' was ambiguous, it could have
9 decided to clarify the meaning of the term in the
10 document itself."

11 So they had the ability to define it.

12 A. Yes.

13 Q. And you then say -- the last paragraph --
14 "I agree with Drs. Wall and Brown," and they had
15 written a letter taking the same position you were
16 taking, hadn't they?

17 A. An article, yes.

18 Q. And that's Dr. Lewis Wall in St. Louis?

19 A. Yes.

20 Q. "I agree with Drs. Wall" --

21 And I'll just ask you a question.

22 Dr. Wall is a noted national ethicist, an expert
23 in medical ethics, isn't he?

24 A. Yes.

25 Q. And he was in agreement with you, wasn't

1 he?

2 A. Yes.

3 Q. "I agree with Drs. Wall and Brown that
4 ACOG can and should do better. The appropriate
5 action on the part of ACOG at this time is to
6 restore the wording of the original practice
7 bulletin, to emphasize the truly experimental
8 nature of these procedures, and to stand behind
9 its promise to women in its own bylaws by serving
10 as a strong advocate for quality healthcare for
11 women and maintaining the highest standards of
12 clinical practice."

13 And --

14 MR. BALL: What's happening here,
15 Your Honor? He's standing here reading, facing
16 the jury. He's just testifying. That's not the
17 way trials are supposed to work.

18 THE COURT: I'm going to -- I'm
19 going to ask -- I think it's -- the cat's already
20 out of the bag. I'm going to ask you to strike
21 from your mind, if you can, that last statement he
22 made. He was just reading from that
23 documentation. He's not asking her questions
24 about it.

25 MR. SLATER: I was about to. He

1 interrupted me, Your Honor.

2 THE COURT: Well, don't read the
3 whole thing. She's got a copy of it up there.
4 Just ask her about it, what her opinion was or
5 whatever.

6 Q. (By Mr. Slater) Do you have an opinion
7 as to whether or not the original bulletin that
8 you authored was correct or incorrect in using the
9 word "experimental"?

10 A. It was correct.

11 Q. Since that time, you've had the
12 opportunity to read hundreds of thousands of pages
13 of documents from Ethicon and Johnson & Johnson?

14 A. Yes.

15 Q. And to see their deposition testimony and
16 learn things you didn't know?

17 A. Yes.

18 Q. As a result of that additional
19 information, please tell the Court and the jury
20 whether there's been any change in your opinion
21 and where your opinion is now.

22 A. The only change in my opinion is that
23 this product and procedure of the Prolift should
24 not even be experimental; it should not be used in
25 women, period.

1 Q. Why?

2 A. Because it's unsafe.

3 Q. And I want to ask you this: You've given
4 a lot of information to us today. Do you have an
5 opinion, to a reasonable degree of medical
6 certainty, as to whether or not the Prolift system
7 was a defective medical device product?

8 A. Yes, I do have an opinion.

9 Q. And what's that opinion?

10 A. That it -- that it was defective in
11 design.

12 Q. And why is that? Explain the foundation
13 for that a little more. You've talked but we want
14 to make sure we have a little bit here too.

15 A. Because in the design intent, the -- the
16 intent of the procedure was to accomplish things
17 that in literal fact could not be accomplished.

18 To place the Prolift mesh in a way that
19 lay flat to reduce the complications, because if
20 the mesh isn't laying flat, it's not safe.

21 To have the mesh in a condition where the
22 pores allow the ingrowth of tissue, and that's not
23 what happened. The pores collapsed, and instead
24 you had this intensified inflammatory reaction,
25 the bridging fibrosis that scrunches the mesh

1 together, mesh erosion, infection of the mesh.

2 When it's necessary to remove the mesh,
3 something that can -- is difficult, if not
4 impossible.

5 These are all things that are part and
6 parcel of the Prolift procedure that could not be
7 improved. They could not be mitigated.

8 They had insufficient warnings --

9 MR. BALL: Your Honor, I will
10 object on the basis that this is repetitive to
11 what we heard three hours ago --

12 THE COURT: Yes, it --

13 MR. BALL: -- plus another
14 narrative response. We can't go over and over the
15 same things.

16 THE COURT: Okay. I'm going to
17 sustain your objection.

18 MR. BALL: Thank you.

19 THE COURT: Now, please go to
20 something else. She has pontificated on that at
21 least two times today, so let's go to something
22 else.

23 She doesn't like it. She wouldn't use
24 it. I understand that. And she's told the jury
25 that.

1 Q. (By Mr. Slater) Do you have an opinion,
2 to a reasonable degree of medical certainty, as to
3 whether the Prolift medical device system was
4 unreasonably dangerous?

5 MR. BALL: That's the same
6 question.

7 MR. SLATER: It's a different
8 question I have to cover for the record. I have
9 to make sure that I have an adequate record.

10 THE COURT: All right. One time.
11 You do it again and I'm going to --

12 You ask -- ask it now. Bear in mind
13 you've done it.

14 MR. SLATER: That's all I plan to
15 do.

16 THE COURT: All right. Do it.

17 MR. SLATER: And I was going to
18 say, for the reasons you've already stated, and I
19 wasn't going to go through it again.

20 THE COURT: Yeah. All right.
21 Appreciate it.

22 Q. (By Mr. Slater) Do you have an opinion,
23 to a reasonable degree of medical certainty, as to
24 whether the Prolift system was an unreasonably
25 dangerous medical device system?

1 A. Yes, I do.

2 Q. And is that for all of the reasons and
3 all the issues that you've provided to this jury
4 today?

5 A. Yes.

6 MR. SLATER: Your Honor, I don't
7 know what time you wanted to break. I'm fine to
8 keep going, but I just want to -- now is a --

9 THE COURT: You want a break now?

10 MR. SLATER: I'm going to go on to
11 a new subject.

12 All right. We'll keep going.

13 THE COURT: Huh?

14 JUROR: No.

15 THE COURT: No?

16 Okay. Well, how -- how much -- well,
17 soldier on. When somebody tells me we want a
18 break, we'll take a break, okay?

19 Q. (By Mr. Slater) Dr. Weber, I've handed
20 you Exhibit P1624. Is that an internal Ethicon
21 PowerPoint you're familiar with?

22 A. Yes.

23 Q. And is this document of significance to
24 you?

25 A. Yes.

1 Q. And what I'd like to do is ask you who
2 authored this document and what's its title.

3 A. This was authored by Dr. Arnaud. He is
4 the scien- -- excuse me, scientific director of
5 Gynecare in Europe.

6 Q. And let's put it up on the screen.

7 A. And the title is "Graft or No Graft."

8 Q. And what I'd like to do is we see the
9 cover there, and let's go to the fourth page.
10 That says "Primum Non Nocere" at the top. What
11 does that mean?

12 A. That's a Latin phrase that means "First,
13 do no harm."

14 Q. And in what community is that Latin
15 phrase known?

16 A. In medicine. It's part of the
17 Hippocratic Oath.

18 THE COURT: Correct.

19 Q. (By Mr. Slater) And we can see that
20 document and I want to just ask you about the
21 bottom of it.

22 It says "Whatever the treatment, it must
23 not create serious complications."

24 That's what Axel Arnaud wrote in January
25 of '05?

1 A. Yes.

2 Q. In your opinion, did the Prolift meet
3 that standard?

4 A. No. Not at all.

5 Q. And is that one of the bases for your
6 opinions on design defect as you've given them?

7 A. Yes.

8 MR. SLATER: Now, I'm going to put
9 up a PowerPoint. Would you like to see it before
10 I put it up?

11 MS. JONES: Do you mind?

12 MR. SLATER: No, I don't mind.

13 MR. BALL: Your Honor, can I ask a
14 question of everybody here as soon as they're done
15 with that?

16 THE COURT: Sure. You want a
17 sidebar here?

18 MR. BALL: Please.

19 (Counsel approached the bench and
20 the following proceedings were held outside the
21 hearing of the jury:)

22 MR. BALL: Your Honor --

23 THE COURT: Yes.

24 MR. BALL: -- we're now at 2:30
25 plus --

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1 THE COURT: Yes.

2 MR. BALL: -- and Dr. Weber has
3 expressed her opinion on multiple occasions that
4 the product is defective and unreasonably
5 dangerous, it has a bad design, et cetera, and
6 she's given reasons for that repeatedly.

7 THE COURT: And I've let almost
8 all of that in.

9 MR. BALL: I don't know why -- I
10 don't think it's appropriate to continue, after
11 the opinion's been given and after the basis for
12 her opinion -- there's no principle in Missouri
13 law that --

14 MR. SLATER: I was about to start
15 failure to warn.

16 THE COURT: What?

17 MR. SLATER: I was about to start
18 failure to warn.

19 THE COURT: Failure to warn.

20 MR. SLATER: Yeah. I just showed
21 Ms. Jones a list of what the medical affairs
22 director said they were supposed to do in their
23 warnings.

24 MR. BALL: Okay.

25 THE COURT: Okey-doke.

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1 MR. BALL: Then I'll withdraw that
2 for right now.

3 THE COURT: When you get done with
4 that, where else are we going with her?

5 MR. SLATER: We have to go through
6 Mrs. Budke's suffering and horrible death. She
7 suffered and died. I need the jury to understand
8 how that happened.

9 THE COURT: But this is going to
10 be the last of the general professional --

11 MR. SLATER: Sorry?

12 THE COURT: This is the last phase
13 of your general professional questions for her is
14 failure to warn?

15 MR. SLATER: And then I have
16 obviously the damages which, you know, she's going
17 to need to teach to the jury because it's a
18 catastrophic situation.

19 THE COURT: Okay. And then we're
20 going to go on and talk about her and get out of
21 this generalized thing?

22 MR. SLATER: Then I'm -- you'll
23 probably put me in jail by then, so I'm just going
24 to --

25 MR. HYDE: That's what I was

1 thinking.

2 THE COURT: Okay. All right.

3 We'll go back.

4 (The proceedings returned to open
5 court.)

6 MR. SLATER: Okay. You can put it
7 up.

8 Q. (By Mr. Slater) Dr. Weber, we've put up
9 a PowerPoint titled "Ethicon Warning Standards,"
10 and would you please tell the jury why you had us
11 put that up there?

12 A. Yes. So in the --

13 MR. BALL: Your Honor, Your
14 Honor --

15 THE COURT: Yes.

16 MR. BALL: -- our objection to
17 that is this: That you are the one that gives the
18 law on what the warning is supposed to be.

19 MR. SLATER: Your Honor, can we
20 have a sidebar?

21 THE COURT: Oh, yeah, sure, let's
22 do a sidebar. I like the noise.

23 (Counsel approached the bench and
24 the following proceedings were held outside the
25 hearing of the jury:)

1 MR. BALL: Okay. Our objection is
2 that you -- you are the one that -- you establish
3 the law on what the warning duty is, and what he's
4 trying to do through a PowerPoint here -- and I
5 don't care whatever Ethicon said. They don't
6 establish the duty in this courtroom. The duty
7 for us is to give an adequate warning. That's it.

8 And he has principles that -- it's what
9 we argued back in the motions in limine back in
10 November, and this is where it's all coming to
11 roost now is he can't create a duty that's beyond
12 the law, and that's what he's doing now.

13 Our only legal duty is to give an
14 adequate warning, and he's trying to create a duty
15 beyond that.

16 THE COURT: Well, he's going to
17 have the same opportunity to do MAI instructions
18 as you all are, and I'm going to give the law on
19 it, which I think that's my duty to do.

20 MR. BALL: It is, but this is --
21 and this is putting in front of the jury --

22 THE COURT: Yeah.

23 MR. BALL: -- something that's
24 beyond the Missouri legal standard.

25 He's trying to have this witness testify

1 as to what the standard should be or what Ethicon
2 said it should be, and that's not the law.

3 MR. SLATER: These are industry
4 standards.

5 MR. BALL: That's not her job.

6 MR. SLATER: These are Ethicon's
7 own standards, their own industry standards.

8 THE COURT: That doesn't matter to
9 me whether they are or not because I've got to
10 give the law on it, and they can look at those and
11 tell whether they meet it or not. They're
12 supposed to follow the law as I read it to them.

13 MR. SLATER: Judge, so I have a
14 strict liability failure to warn claim, I have a
15 negligent failure to warn claim, and I have
16 punitive damage claims, and I'm not allowed to
17 show the jury that they violated their own
18 standards?

19 He can argue whatever he wants to argue.
20 He's telling you what the facts are. We have a
21 difference of opinion on that, and the jury will
22 decide, but we're allowed to have evidence of what
23 they were supposed to do based on their own
24 testimony. This is what we were supposed to do.

25 I can't tell the jury what they thought

1 they were supposed to accomplish?

2 MR. BALL: She -- she can say, "I
3 believe that the warning is inadequate because it
4 didn't have this, it didn't have this, and it
5 didn't have that," but what she can't do is get up
6 here and then say --

7 THE COURT: And say "This one and
8 this one and this one."

9 MR. BALL: Right.

10 MR. SLATER: Why not?

11 MR. BALL: All she can say is --

12 MR. SLATER: I don't understand.

13 With all due respect, I don't understand.

14 THE COURT: She's formed an
15 opinion on what they did wrong --

16 MR. SLATER: And she's relying, in
17 part, on their own internal standards to show they
18 violated their own standards. This is a punitive
19 damage issue. This is outrageous. They violated
20 all their own standards.

21 Now, if they want -- if they want to get
22 an expert to get up there and say Ethicon's
23 standards are -- were too high, they can put on a
24 witness to say that. This is Mr. Ball testifying.

25 THE COURT: No.

1 MR. SLATER: And honestly, with
2 all due respect, he hasn't worked on this case.
3 He doesn't know this. He doesn't know -- he --

4 THE COURT: I know you've worked
5 on these cases a lot.

6 MR. SLATER: How can --

7 THE COURT: I understand that.

8 MR. SLATER: How can I not tell
9 the jury their own internal standards for
10 warnings, Judge? They're experts in the field.
11 That's what they do for a living is they make
12 warnings. They're -- and I'm not going to say it,
13 but this is all under the FDA regulations and
14 they're trained by that and that's what they're
15 supposed to be meeting and this is what they're
16 supposed to do by law.

17 I mean, I don't understand. These are
18 the standards by law that they have to meet.
19 Mr. Ball is telling you these exceed the law of
20 the state of Missouri. I don't agree. The law in
21 Missouri is very easy. They decide what's
22 adequate or not.

23 And one of the evidential connectors is,
24 the company says "We're supposed to warn of XYZ."
25 The jury can consider that as evidence. I'm not

1 saying it's dispositive, but it's evidence of
2 whether or not they met the standard of care and
3 whether they violated the failure to warn strict
4 liability.

5 MR. BALL: I've handled a lot more
6 warnings cases in Missouri than Mr. Slater has,
7 and what an expert is supposed to do is come up
8 and say do they believe the warning is inadequate?
9 No. Why not? Because it's missing this or it's
10 missing that or --

11 THE COURT: That's what I'm
12 saying.

13 MR. SLATER: But I have to lay a
14 foundation for it.

15 MR. BALL: No, you don't.

16 MR. SLATER: Oh, of course if I
17 put my foundation in, they would move to strike
18 the opinion. The problem is they violated their
19 own standards.

20 THE COURT: No, I'd have to strike
21 it.

22 MR. SLATER: Judge, you're not
23 going to let me show the jury they violated --

24 MR. BERGMANIS: No. He's agreeing
25 with you.

1 MR. SLATER: Oh, oh, I --

2 MR. BALL: No, he's not.

3 THE COURT: No, no, no. I wasn't
4 agreeing with putting that up and publishing it.

5 MR. SLATER: Judge, it's a
6 PowerPoint summary of testimony that's coming into
7 evidence.

8 MR. BALL: There's a correct way
9 to do this and a wrong way to do it, and the
10 correct way is to say "It's inadequate because
11 it's missing this and it's missing that" and
12 "What's your basis for that?" "Based on my
13 experience, it should include this and that kind
14 of thing." That's the right way to do it.

15 MR. SLATER: And the right way to
16 do it is to say, "And let me tell you why I think
17 that. I'm relying on certain things. I'm not
18 just pulling these opinions out of thin air." And
19 she's not.

20 THE COURT: She can do that.

21 MR. SLATER: I don't want her to
22 pull everything. I want her to --

23 THE COURT: You want her to stand
24 there and go one, two, three, four, five down the
25 line.

1 MR. SLATER: I want the jury to
2 hear what the standards are that the company held
3 itself to so she can say, "I don't think they
4 adequately warned and they violated their own
5 standards" --

6 (Court reporter interruption.)

7 MR. SLATER: And by the way, they
8 never -- whatever. I'm not even going to go
9 there. I'm not going to say it.

10 I've never heard an objection that I
11 can't, in any case -- that you can't tell the jury
12 the defendants' own standards, what they were, and
13 whether or not they met them.

14 MR. BALL: You give --

15 MR. SLATER: It's evidence. It's
16 not dispositive --

17 MR. BALL: You give the law in the
18 case.

19 MR. SLATER: Of course you give
20 the law, adequate warning in Missouri.

21 It's evidential, Your Honor. It's
22 something that she can say --

23 THE COURT: She's got to know what
24 they -- what they say and what they -- she can
25 testify as to what --

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1 MR. SLATER: Are they going to
2 cross-examine her and try to impeach her
3 credibility of not knowing what she's talking
4 about? Darn right.

5 THE COURT: Okay.

6 MR. SLATER: And I mean -- and I'm
7 getting cut off at the knees here. I mean,
8 they're going to come after her.

9 I'll tell you what it is. They're going
10 to say, "Dr. Weber, that's your opinion and why
11 don't you just hold that opinion," and they're
12 going to -- and she's not going to be able to show
13 the jury all the Ethicon statements they violated?

14 I mean, I can't -- I've got to be able to
15 make my case. This is evidence that's devastating
16 evidence in the sense that they violated their own
17 standards and they want to keep it out. They have
18 no basis to. Show me a case.

19 MR. BALL: Your Honor, we run into
20 this all of the time because he wants to do --

21 (Court reporter interruption.)

22 MR. BALL: What if we had a
23 standard that said the warning should be
24 absolutely perfect, okay?

25 THE COURT: Yes.

1 MR. BALL: That would not be the
2 law.

3 THE COURT: No.

4 MR. BALL: And he would be putting
5 in front of them that.

6 And that's what he's doing here. He's
7 holding -- he should just have her say the way it
8 is done in every other case: The warning is
9 adequate because it didn't contain this and this
10 and this and that's the way I feel about it, and
11 that's it.

12 (Court reporter interruption.)

13 MR. BERGMANIS: Can you tell them
14 what their standard was? What the company's
15 standard was?

16 MR. BALL: That's irrelevant
17 because you give them the standard.

18 MR. BERGMANIS: Whoa, whoa, whoa.
19 You give them jury instructions. You're mixing
20 jury instructions with the standard. The
21 standards is what they have. The company
22 standard.

23 MR. BALL: You can't put in front
24 of the jury some other standard other than what
25 the law is because that's what it is.

1 MR. SLATER: Are you serious? Are
2 you serious?

3 MR. BERGMANIS: That's jury
4 instructions versus the company policies.

5 MR. SLATER: I deal with industry
6 standards all the time. Industry standards -- I
7 mean, this is their legal obligations, Judge,
8 under the FDA regulations. I'm not going to say
9 that.

10 THE COURT: I was trying to give
11 you wide latitude in asking her about them. I
12 just don't want those things put up there on the
13 board. You're going to have a copy of them in.

14 MR. BERGMANIS: Can you put them
15 in front of her and ask her to go through them? I
16 mean, just say --

17 MR. SLATER: Oh. So she can say
18 them? She just can't put them on the screen?

19 MR. BERGMANIS: Just -- yeah. Put
20 them in front of her and have her go down the
21 list.

22 THE COURT: She can talk about
23 them generally. I just don't want her to start
24 reading the list.

25 MS. STRAUSS: Judge, she is not

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1 somebody who can talk about this.

2 THE COURT: What?

3 MS. STRAUSS: She is not somebody
4 who knows about internal company standards. She's
5 not a company person.

6 MR. SLATER: She's studied this
7 stuff for four years --

8 THE COURT: I'm willing to let
9 her --

10 MR. SLATER: -- and every one of
11 the medical affairs doctors is also a
12 gynecologist.

13 MR. BERGMANIS: Just let her have
14 it and go through the list, but don't put it up.

15 THE COURT: Yeah. Let's do that.
16 Can we do that?

17 MR. SLATER: I'll do whatever you
18 tell me.

19 THE COURT: All right. Well,
20 let's do that. We're burning daylight.

21 MR. SLATER: Well --

22 THE COURT: Well, I mean, that's
23 all right too. I don't care. You can burn it all
24 you want.

25 (The proceedings returned to open

1 court.)

2 THE COURT: Let's do what I
3 suggested. Yeah. We're going to take a break at
4 3:00, so wherever you -- whatever you're doing.

5 Okay. If -- let's give it about a
6 12-minute shot here and then we'll take it up
7 after they have their break.

8 MR. SLATER: You know what, Judge?
9 Now is probably a good time. If you're going to
10 do it in 10 minutes, now is a good time to break.

11 THE COURT: Well, all right.
12 Let's just go -- we'll take -- let me read this.
13 We'll do it till 3:00.

14 Justice requires that you not make up
15 your mind about the case until all the evidence
16 has been seen and heard. You must not discuss
17 this case among yourselves or with anyone else or
18 comment on anything you hear or learn in this
19 trial until the case is concluded and you retire
20 to the jury room for your deliberations.

21 Also, you must not remain in the presence
22 of anyone who is discussing the case when the
23 court is not in session.

24 And having said that, go ahead and take a
25 break and if you would be back up here at 3:00.

1 (The following proceedings were
2 held in the courtroom outside the presence of the
3 jury:)

4 THE COURT: Hey, before you all
5 leave, I want to talk to the -- to everybody that
6 represents a different client.

7 THE REPORTER: Do you want it on
8 the record, Judge?

9 THE COURT: You bet I do.

10 THE REPORTER: Okay.

11 THE COURT: As many as want to
12 from each side, come up.

13 If y'all will come up here because I
14 don't want to holler or get to talking real loud.

15 I'm not the sharpest knife in the drawer,
16 I'm sure. I'm sure there are better -- much
17 better judges in the state of Missouri than I am,
18 but I will try to follow the law. I really will
19 do that. And I will try to give you an equal
20 opportunity, and you an equal opportunity, and I
21 don't have a dog in this fight, but here's the
22 whole thing.

23 We're spending much more time than I've
24 spent in any case up here at this deal. I thought
25 the boat case that I had last month was something,

1 but it pales besides this.

2 I know what you want to do and I know
3 what your pleadings ask for, but there's a right
4 way and a wrong way to do it and I don't think
5 putting that thing up there and having her get up
6 and say this -- "I think this" and "I think this"
7 and "I think this is what caused this," because
8 that is a -- that's a -- that's a factual matter
9 that the jury's got to determine. Or maybe it's
10 not that way in New Jersey. I don't know.

11 MR. SLATER: Don't I -- don't I
12 have the right to put expert opinion on on the
13 failure to warn?

14 THE COURT: Yeah. And that's why
15 I took --

16 MR. SLATER: That's what I'm
17 trying to do.

18 THE COURT: Oh, I thought you were
19 just wanting to -- her to go down through there
20 and affirm everything that you asked about.

21 MR. SLATER: No. I wanted to use
22 that as the framework in which to analyze their
23 warnings so that I could show that -- the jury
24 that they violated their own warning standards.

25 THE COURT: Well, you can do that

1 without putting that up there.

2 MR. BALL: Your Honor, I -- we
3 continue to believe that the appropriate way to do
4 this is for her to state an opinion that the
5 warning was inadequate --

6 THE COURT: Was inadequate and
7 then --

8 MR. BALL: -- and to give -- and
9 to give reasons for it without reference to --

10 Our internal standards do not set the
11 standard in the state of Missouri for whether a
12 warning is adequate or not.

13 MR. SLATER: I'm not saying they
14 set the standard but they're evidence that can be
15 considered by the jury, right?

16 THE COURT: Well, that's why I was
17 going to let you give them --

18 MR. BERGMANIS: I think we just
19 give her copies and she looks at it, and he'll
20 have a copy, and go through the list --

21 THE COURT: Yeah. And we don't
22 have to go through all this.

23 MR. BALL: So -- and the other
24 thing I'll say is that she's supposed to state
25 this based on her professional opinion.

1 THE COURT: Yes. And you're going
2 to have to ask her "Is this based on your
3 professional opinion?"

4 MR. SLATER: Of course.

5 THE COURT: I mean, that's part of
6 it.

7 MR. SLATER: But she's allowed to
8 rely, in part, on the standards in the industry.

9 MR. BALL: And then so instead, so
10 she's getting up there taking something from a
11 PowerPoint of ours and trying to --

12 MR. SLATER: It's not your
13 PowerPoint.

14 MR. BALL: -- say that --

15 MR. SLATER: It's actually a --

16 I'll tell you what the PowerPoint is.
17 Each one of them is footnoted with the pages and
18 lines of the deposition testimony from the medical
19 affairs director who testified to the standard.
20 These are all admissions.

21 MR. BALL: See, so this is what
22 he's doing is again he's got a medical expert up
23 here being a mouthpiece for his interpretation of
24 company documents and company testimony.

25 MR. SLATER: Isn't --

1 MR. BALL: That's not what is
2 supposed to be permitted. It was partially
3 covered in that brief that we gave you this
4 morning. This is supposed to be a medical expert
5 talking about the product and the warnings on the
6 product, and that is what it's -- all it's
7 supposed to be about, and we've gone on and on and
8 on and repetitive multiple times.

9 MR. SLATER: I haven't even gotten
10 to go there at all. I've -- I don't understand
11 how it is that the jury doesn't get to hear that
12 they had standards among the medical affairs
13 people, who are doctors just like her, who are
14 responsible to make sure the warnings were
15 adequate and had sign off on every warning. She's
16 in the same profession as them. They were at the
17 top of the pyramid on deciding what was what, in
18 terms of the medical information and making sure
19 that the standards were met.

20 She's perfectly qualified. She's
21 certainly a heck of a lot more qualified than
22 Charlotte Owens, who was four years out of her
23 residency when she was letting the Prolift go on
24 the market.

25 THE COURT: Well, I thought you

1 made a pretty good point on that, and --

2 MR. BERGMANIS: He did. He's --

3 THE COURT: Yeah.

4 MR. SLATER: I'm just saying I
5 don't understand how they can argue that she can't
6 rely on their standards, in part, to say, "Look,
7 this isn't just my opinion" --

8 THE COURT: Here's what I want. I
9 don't want to get into things like this:
10 "Specific example of an improper and inadmissible
11 opinion would be if Ethicon were truly committed
12 first and foremost to patient safety, Ethicon
13 would not have ignored these compelling findings
14 in the literature and would have appropriately
15 studied and tested this known phenomenon to
16 determine whether the product could be safely
17 manufactured and given the nature of this design
18 characteristic and, if so, corrected all the
19 IFUs for its mesh product that included false
20 claims."

21 MR. BALL: Yeah. He's -- that's
22 what we've been --

23 MR. SLATER: I'm not sure where
24 you're reading from. Is that their brief?

25 MR. BALL: Yeah.

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1 THE COURT: What's that?

2 MR. BALL: No. That's from your
3 expert's report.

4 MS. STRAUSS: Her testimony.

5 MR. BALL: From your expert's
6 report.

7 We've been going -- that's what's been
8 happening all day long.

9 MR. BERGMANIS: That's not what's
10 going on --

11 MR. BALL: That's what's been
12 happening all day long and what's going to --

13 MS. GUNN: I'm just trying to
14 figure out what they're --

15 They're worried about something that
16 might happen in the future, if those --

17 MS. STRAUSS: No.

18 MR. BALL: No.

19 MS. STRAUSS: Parts of that have
20 already happened today.

21 MR. SLATER: The only issue before
22 the court --

23 MS. GUNN: No.

24 MS. STRAUSS: Yeah.

25 MR. SLATER: -- is whether or

1 not --

2 Your Honor, I'll respect -- I'll do what
3 you said. I won't publish it. But certainly she
4 can rely on it, and that's all.

5 THE COURT: You're going to get
6 most all of it in the record by the time you talk
7 to her about it.

8 MR. SLATER: But I need my --
9 obviously I need my expert to give an opinion.
10 See, they're going to cross her and say,
11 "You don't know anything about warnings."

12 THE COURT: I thought you said --
13 I thought that's what we talked about is you've
14 said, "Doctor, do you have an opinion?"

15 MR. BERGMANIS: We're good.

16 THE COURT: Okay. You and Erik
17 talk about this. He's got -- you know, it's
18 better -- it's better for the guy who knows the
19 SOB than the guy who doesn't, but you can come out
20 on this. Believe it or not, you can.

21 I don't -- I'm not here just -- I didn't
22 come here just to want to fight with you. As an
23 old senior judge, you know, I'd rather be fishing,
24 but I'm not. I'm here and I'm in the middle of it
25 and there ain't no backing out now.

1 So all I'm saying is, you seem to me like
2 a very intelligent lawyer. Just ask the doctor,
3 "Do you have an opinion about this?" "Do you have
4 an opinion about that?" "Do you have an opinion
5 about this?" "If so -- if they said so-and-so, do
6 you have an opinion as to whether that's" --

7 MR. SLATER: I plan to do that.

8 THE COURT: -- "medically
9 certain?"

10 MR. SLATER: I plan to do that,
11 but obviously they're going to cross her and say,
12 "Well, you don't have any basis for that," and so
13 they need to know the basis.

14 THE COURT: Well, I'm not --

15 MR. BALL: If we cross-examine and
16 open something up, then -- then he's --

17 THE COURT: I'll give you plenty
18 of time. I'll even let you voir dire or whatever
19 you need to do.

20 MR. SLATER: I was going to be
21 done at 3:30, but for all these objections.

22 THE COURT: Well, I would -- I'd
23 love to woulda-coulda-shoulda, but we're not going
24 to get there that way, I don't think.

25 Yeah. Cut her down.

1 (Recess taken from 2:54 p.m. to 3:05 p.m.)

2 (The following proceedings were
3 held in the courtroom outside the presence of the
4 jury:)

5 THE COURT: Okay. I guess
6 Mr. Ball and Ms. Christy, if y'all would come up,
7 we're going to -- tell them I'll be with them in
8 just a minute. I just -- I'd rather do this as to
9 have them have to sit here while we play horse.

10 THE BAILIFF: You want them out?

11 THE COURT: No. I'll be -- yeah.
12 Okay.

13 THE BAILIFF: No. They're fine.

14 THE COURT: Now, you want to come
15 back up here, Mr. Slater, and --

16 Let's see now. Have we got one of
17 everybody?

18 Okay. Now, let's start what we -- what
19 you and Ms. Bettina started to talk about and then
20 we decided to wait till we got everybody here and
21 leave the jury out.

22 Okay. Mr. Slater.

23 MR. SLATER: Thank you, Your
24 Honor.

25 I have presented to Your Honor the IIS

1 study agreement that was discussed earlier between
2 Ethicon and Vincent Lucente, who is the person who
3 actually gets paid the money. He's the person on
4 the contract.

5 THE COURT: It must not have been
6 much of an agreement if it was \$12,500.

7 MR. SLATER: Well --

8 THE COURT: You got people that
9 charge that much an hour, almost, here.

10 MR. BALL: Not quite.

11 MR. SLATER: So what they were
12 doing was they were paying for his support staff
13 and the access to computers and stuff so that they
14 could crunch the data and run the databases --

15 THE COURT: Okay.

16 MR. SLATER: -- so that they could
17 study this data, and he went to Ethicon and said,
18 "Will you fund this for me so that I can have this
19 done?"

20 And this agreement was reached whereby
21 Ethicon said okay, and you've seen the agreement.
22 There's several important provisions.

23 One, "The company has unrestricted access
24 to the data and may use it for any purpose it
25 deems fit in compliance with applicable laws." So

1 they had absolute access to it.

2 His testimony was they never looked at
3 it. Which is negligent, in and of itself, in
4 our -- in our view.

5 THE COURT: In your view.

6 MR. SLATER: In our view, and I
7 think it's -- I think, you know, that's what -- to
8 tell you our view, but we think that a jury could
9 believe it would be negligent not to look at the
10 data after they contracted and had the right to
11 look at it.

12 Number two, it provides that he is
13 required -- not "may," but "will seek to publish
14 in the peer-reviewed literature the results of the
15 study." That did not happen. It was never
16 published in the peer-reviewed literature. We
17 have his depo- --

18 THE COURT: You know for
19 definite -- oh, go ahead.

20 MR. SLATER: Yeah. We do. We
21 know it was not published in the peer-reviewed
22 literature.

23 And there are some other provisions about
24 publishing the full data. This was a set of 514
25 patients. They never ever published an article on

1 it. It's in the deposition. Dr. Weber has read
2 it. I took the deposition. They never ever
3 published all the patients in one study.

4 They couldn't answer questions to us as
5 to some abstracts they put out as to how many
6 patients came from this group and how many
7 patients came from other databases.

8 It showed very serious issues, and
9 Dr. Lucente's articles are very important evidence
10 that the company has used over the years to
11 support the safety of the products, and in fact,
12 we learned things in this -- from this study that
13 showed that Dr. Lucente didn't follow what's
14 called good clinical practice and didn't do things
15 the right way from a -- from an investigator's
16 standpoint as a scientist, and he was the primary
17 investigator or one of the primary investigators
18 for the two pilot studies.

19 The Gynemesh and TVM studies that allowed
20 this to be marketed, in Ethicon's view, where they
21 were studying the prototypes, he was one of the
22 investigators, which obviously when Dr. Weber
23 tells the jury, you know, he published -- and I
24 don't have the PowerPoints in front of me but I
25 think he disclosed in an abstract of a part of the

1 patients about a 13% recurrence rate.

2 She went through the data and she
3 analyzed it at the highest level possible and
4 found that 49% of the patients at one year had
5 recurrence of prolapse, which is an astronomical
6 number, and it would be very damaging in many ways
7 to the defense and it's a very strong fact for us
8 in many ways, not just to show that the product
9 didn't work very well but also to show that
10 Dr. Lucente had some serious issues with the
11 veracity of the data he published.

12 And as Your Honor -- I think we told you
13 earlier, we have -- we have testimony from the
14 medical affairs director, who was the corporate
15 representative of the company, that he admitted he
16 did not believe certain data published by Lucente
17 on erosion rates, and that's another problem.

18 Lucente's group published in some studies
19 that they had patients being studied and they had
20 zero erosions, or 1.1% erosions, and Hinoul, the
21 corporate rep, said, "I don't believe those
22 numbers."

23 So this is a guy who also taught
24 Dr. Simpson and she relied on his statements about
25 what the safety was.

1 THE COURT: Which doctor?

2 MR. SLATER: Dr. Lucente. The guy
3 who contracted with the company --

4 THE COURT: Oh, okay, okay.

5 MR. SLATER: -- taught
6 Dr. Simpson, and she testified at length that she
7 relied on him to give truthful information about
8 the data that supported the product and what were
9 the real complication rates and she was led to
10 believe that day it was a 5% erosion rate.

11 This data shows that he has over a 10%
12 erosion rate on his own patients. His recurrence
13 rate was far higher than what she was led to
14 belief.

15 THE COURT: Dr. Lucente?

16 MR. SLATER: Dr. Lucente.

17 So it's a -- he's a central figure in
18 this case for a lot of reasons, and this data
19 shows that his patients had very high complication
20 rates that he never disclosed, didn't disclose to
21 Dr. Simpson, and obviously that's an important
22 issue on the learned intermediary issue, and I
23 think that we should have the right to be able to
24 show the jury the truth of the data, and the
25 defense has the right to come in and challenge

1 Dr. Weber and say she didn't add up the numbers
2 right, or whatever it is.

3 And, you know, if they had a witness they
4 could bring somebody in. I don't think they have
5 any witnesses who actually did what Dr. Weber did,
6 so there's nobody they can bring in, but that's
7 their choice.

8 And I think it's -- it's an important
9 fact for the jury to hear and then the chips will
10 fall where they may.

11 That's our argument, Your Honor.

12 THE COURT: Now, in order to get
13 to that information, you're going to ask her
14 questions to a reasonable degree of medical
15 certainty?

16 MR. SLATER: Of course.
17 Absolutely.

18 THE COURT: And you're not going
19 to publish that thing?

20 MR. SLATER: I'll just have her
21 speak it to the jury.

22 MS. JONES: May I respond, Your
23 Honor?

24 THE COURT: Yes, ma'am.

25 MS. JONES: There are several

1 issues about the admissibility of this.

2 Mr. Slater represented to the Court
3 earlier -- and I want to make this clear and I
4 want to say it carefully because Mr. Slater has
5 accused me of making a misstatement, and just so
6 the record is clear.

7 Mr. Slater has suggested repeatedly that
8 Ethicon owned this data. If you look at
9 Paragraph 7 of this contract --

10 THE COURT: Agreement?

11 MS. JONES: -- of the agreement --

12 THE COURT: Uh-huh.

13 MS. JONES: -- it provides that
14 the institution, which is defined as the doctor
15 and the clinic, had --

16 THE COURT: They were the ones who
17 were going to run it.

18 MS. JONES: -- they were the
19 owners of the data.

20 THE COURT: I'm sorry.

21 MS. JONES: That Ethicon does have
22 -- did have access to it, but Ethicon was not the
23 owner of the data. It was not produced from
24 Ethicon's files.

25 That's number one.

1 THE COURT: In other words,
2 whatever the data was came from the other party.

3 MS. JONES: Came from Dr. Lucente.

4 THE COURT: Okay.

5 MS. JONES: The second issue is
6 that our obligation -- that our objection to this
7 is an objection that Dr. Weber's analysis, to the
8 extent that it is, is not reliable, has never been
9 published. It's her statement, looking at these
10 documents, about what they show.

11 And in fact, what -- it's not clear,
12 under any circumstances, that this data proves
13 that anything that Dr. Lucente specifically did or
14 didn't do or published or didn't publish is wrong.

15 In fact, Your Honor, this agreement
16 didn't even begin until 2007 and didn't
17 conclude -- or wasn't supposed to conclude --
18 until after Ms. Budke's surgery.

19 THE COURT: Surgery?

20 MS. JONES: So what we're having
21 here is something that I suggest to Your Honor is
22 irrelevant, to the extent that it has any
23 probative value is outweighed by the prejudicial
24 effect, that it's not been something that's been
25 published or reviewed by anybody other than

1 Dr. Weber, and the suggestion and the implication
2 that Ethicon ought to be tarnished because
3 Dr. Lucente didn't publish the data when, in fact,
4 there's an agreement for him to do so is -- is
5 just wrong. It's irrelevant and it's not -- it's
6 not right under these circumstances.

7 MR. BALL: If I could just kind of
8 add -- chip in just a little bit there, Your
9 Honor.

10 So what we've heard from Mr. Slater he
11 wants to do is, first of all, he wants to say that
12 she did an analysis that showed it had a high
13 recurrence rate, okay?

14 Well, number one, we've -- Dr. Simpson
15 has already said and all the people in the case
16 have already said that there was no recurrent
17 prolapse with Mrs. Budke. It's an erosion problem
18 if there's anything, an infection problem, but
19 there was not a recurrence. So that's number one.

20 THE COURT: All right.

21 MR. BALL: Number two, there's no
22 showing that Dr. Lucente ever had occasion before
23 Mrs. Budke's surgery to have any communication
24 with Dr. Simpson about this data because the data
25 wasn't even done yet.

1 And then number three -- and this is, I
2 think -- well, and then number three is -- as
3 Christy has said, is that she wants to state an
4 opinion that the data shows such and such in terms
5 of rates and yet there's no showing of
6 reliability, there's no showing of standard error,
7 there's no showing -- she hasn't had it
8 peer-reviewed by anybody, she hasn't published it
9 herself.

10 And then the final -- final point is --
11 and probably this is the one that is the most
12 telling on this -- is even if they are allowed to
13 state that "I did this evaluation, here's my
14 opinion," they then want to go to the next step.
15 The next step is that they want to say -- that
16 they want to create the impression that Ethicon
17 hid this from everyone when it was the doctors
18 that decided not to publish it.

19 These are not our employees and they're
20 the ones that made the decision not -- and it's
21 unfairly prejudicial for us for them, through
22 these questions and through the argumentative nature
23 of the questions and the answers, are allowed to
24 stand up there and create testimony or create an
25 impression that we somehow hid these results by

1 not getting them published when it was the doctor,
2 not us, that didn't do that.

3 MS. JONES: Which just to make it
4 clear, Your Honor, the contract is signed in the
5 end of October '07, after Dr. Simpson's training,
6 so the implication that Dr. Lucente somehow lied
7 to her based upon this data is absolutely wrong.

8 MR. BALL: So we have two
9 questions.

10 One is the admissibility of the -- one is
11 the admissibility of the analysis she did, and
12 that; and then the second is, is the line of
13 questions that go anything -- that try to intimate
14 that we hid something or did something improper.
15 Those are the two different questions and the two
16 different objections.

17 MR. SLATER: At this point, Your
18 Honor, what I would seek to do is to have
19 Dr. Weber explain that she studied the data, tell
20 the rates that she found of complications, and
21 I'll stop.

22 THE COURT: And stop right there.

23 MR. SLATER: I'll stop there.

24 THE COURT: If you do that and you
25 don't try to put an innuendo on it, I'm going to

1 let you do it.

2 MR. SLATER: That's fine. And I
3 should --

4 THE COURT: Okay. Because here's
5 the whole -- here's the whole thing. There is
6 some truth in what they say. She died -- I mean,
7 this took place in 2008, as I recall. I've got
8 all those dates here when she had her surgery and
9 when she died. And this -- at best, this contract
10 was for up to 2009.

11 MR. BERGMANIS: Seems like that
12 would be a perfect subject for them to cross her
13 on.

14 THE COURT: Well, they can, but
15 I'm not going to let --

16 I mean, I'm going to let him do what he
17 said he would do --

18 MR. BERGMANIS: Very good.

19 THE COURT: -- okay?

20 MR. BERGMANIS: Thank you, Judge.

21 MR. SLATER: Should I put the
22 agreement into evidence as well, so that at
23 least --

24 MS. STRAUSS: No.

25 MR. BALL: No.

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1 THE COURT: No, I don't think so.

2 MS. JONES: Well, let me --

3 THE COURT: Wait.

4 MS. JONES: But it is -- I think
5 it is important, for the implication and for the
6 accusations that have been made, to show that the
7 agreement is dated in October of 2007 so there's
8 not a question.

9 MR. BERGMANIS: Well, let's put it
10 in.

11 MR. BALL: But -- no. But here --
12 I think what I heard is all he's going to do --
13 all he's going to do is say "I got some data" --
14 "I got some data from this study and I looked at
15 it and here's the recurrence rate," period.
16 That's all he's going to do.

17 MR. SLATER: The erosion rate.

18 MR. BALL: He's not going to
19 read -- he's --

20 MR. SLATER: There's three rates.

21 MR. BALL: Yeah.

22 MR. SLATER: The erosion rate, the
23 recurrence rate, and the reoperation rate.

24 MR. BALL: And we -- just so we're
25 clear, Your Honor, we still object to that but I

1 understand that you're overruling that but you're
2 not --

3 THE COURT: But the thing is, if
4 one of those three did not occur with her, they've
5 certainly got wide latitude in arguing that. I
6 thought this --

7 MR. BALL: Yeah. But --

8 THE COURT: What were the -- I
9 can't remember now the three --

10 MR. BALL: What we don't want --
11 and I think Adam is agreeing not to do this -- is
12 any innuendo that something was being hidden by
13 Ethicon or something like that.

14 If he just does what he's saying here,
15 our objection to that has been overruled and we'll
16 proceed.

17 THE COURT: All right. Well, we
18 know that they -- whatever the information was in
19 there was not available to Dr. Simpson at that
20 time because they hadn't reprinted that new.

21 MR. SLATER: Yeah. I mean, we
22 could -- we could talk chapter and verse on it but
23 I'm going to stick with your ruling, so...

24 THE COURT: Well, you know,
25 because she told you several times -- she told you

1 several times yesterday over there, she said,
2 "I've not -- I can't tell you I've read all those
3 medical articles" any more than I can tell you
4 that I've read everything that's come out of the
5 Supreme Court of Missouri, the court of appeals of
6 every district around here, and the federal court.
7 I haven't.

8 You guys educate me on what I know with
9 stuff like this, you know, but, yeah, if you'll
10 stay in the bounds of what I said, I'm not going
11 to be barking any. Okay?

12 MS. JONES: Okay.

13 MR. SLATER: That's it. I'm going
14 to ask, you know, "You went through the data, you
15 studied it and here's -- tell us the three rates."

16 THE COURT: And do we want that
17 document in or not?

18 MS. JONES: I hate to ask this
19 question.

20 THE COURT: Yeah.

21 MS. JONES: I need 30 seconds to
22 run to the restroom, if you don't mind.

23 THE COURT: Okay. 30 seconds is
24 granted. I'll bring the jury in within one
25 minute. The time starts now.

1 MS. JONES: Okay.

2 (Recess taken from 3:20 p.m. to 3:22 p.m.)

3 (The following proceedings were
4 held in the courtroom outside the presence of the
5 jury:)

6 MS. JONES: Thank you, Judge.

7 THE COURT: Okay. Let's bring the
8 jury in.

9 (The following proceedings were
10 held in the courtroom in the presence of the
11 jury:)

12 THE COURT: Okay. Be seated. I
13 guess all but Mr. Slater. I think he's going to
14 remain standing for a while.

15 And the doctor is taking the stand again
16 with the understanding that she remains subject to
17 the oath.

18 THE WITNESS: Yes.

19 Q. (By Mr. Slater) Okay. Dr. Weber, before
20 we come back and talk about some warnings issues,
21 I want to ask you a discrete couple of questions
22 about the Vincent Lucente IIS database with
23 Ethicon, okay?

24 A. Yes.

25 Q. You had testified to the jury that you

1 reviewed that database and you analyzed the data
2 yourself independently?

3 A. Yes.

4 Q. And would you please tell the jury:
5 Beginning with the erosion rate, what was the
6 one-year erosion rate for Dr. Lucente?

7 A. 10.6%.

8 Q. What was Dr. Lucente's recurrence rate,
9 meaning recurrence of prolapse, at one year?

10 A. 49%.

11 Q. What was Dr. Lucente's reoperation rate,
12 meaning the percentage of patients that were --
13 made it to one year who had a reoperation?

14 A. 29% of the women required another
15 operation after the Prolift.

16 Q. What I'd like to do now is talk to you
17 about certain of the documents that provided
18 information to physicians, okay?

19 A. Yes.

20 Q. We're all familiar with the IFU, the
21 instructions for use.

22 Are you familiar with that document?

23 A. Yes.

24 Q. Okay. Very simply, what was the purpose
25 of that document?

1 A. The purpose of the document was to set
2 out, from Ethicon to doctors, certain critical
3 information about the Prolift.

4 The indications and the
5 contraindications, which means simply who must not
6 have the Prolift and who may be a good candidate
7 for the Prolift; warnings; adverse events; things
8 like that.

9 **Q. Have you formed opinions as to whether or**
10 **not the warnings provided by Ethicon in the IFU**
11 **were adequate?**

12 A. Yes, I have an opinion.

13 **Q. Okay. We're going to go through that and**
14 **I want to just touch on a few other documents.**

15 The patient brochure that we've seen, are
16 you familiar with that?

17 A. Yes.

18 **Q. Do you have opinions about whether those**
19 **warnings and the information provided there was**
20 **adequate?**

21 A. I have opinions, yes.

22 **Q. And with regard to the GPS sales aid that**
23 **we spoke to Dr. Simpson about, are you familiar**
24 **with that document?**

25 A. Yes.

1 Q. And do you have opinions about whether or
2 not that document adequately warned physicians?

3 A. Yes, I have opinions.

4 Q. And with regard to those three documents,
5 what is your opinion?

6 MS. JONES: Your Honor --

7 MR. SLATER: And then I was --

8 THE COURT: Just hold it.

9 MR. SLATER: -- going to explore
10 it. Once I have the opinion, I'll explore it.

11 MS. JONES: Just -- let's go up
12 one second.

13 MR. SLATER: Just tell me what you
14 want to do. I'll do whatever you want.

15 MS. JONES: I just want --

16 (Counsel approached the bench and
17 the following proceedings were held outside the
18 hearing of the jury:)

19 MR. SLATER: I'll do whatever you
20 want.

21 MS. JONES: No, no, no. My only
22 objection is that Ethicon's duty to warn goes to
23 the doctor, and I don't want to waive the
24 objection on the patient brochure. The way it's
25 phrased --

1 MR. SLATER: That's the way I
2 phrased it.

3 MS. JONES: Well, just as long as
4 it's clear and clear for the jury, the duty goes
5 to the doctor, as opposed to the patient.

6 MR. SLATER: Sure.

7 THE COURT: Do that. Thank you.

8 (The proceedings returned to open
9 court.)

10 Q. (By Mr. Slater) Dr. Weber, what is your
11 opinion as to whether or not Ethicon adequately
12 warned physicians in the IFU, the patient
13 brochure, and the GPS sales aid?

14 A. My opinion is that the warnings were not
15 adequate.

16 Q. Okay. And we're going to go through that
17 a little.

18 And with regard to the professional
19 education PowerPoint from 2005 that we've talked
20 about, do you have an opinion about whether that
21 provided adequate warnings to physicians?

22 A. Yes, I have an opinion.

23 Q. And what's that opinion?

24 A. My opinion is that the warnings were not
25 adequate in the professional education.

1 Q. Now, would you please tell the jury:
2 What do you consider in forming those opinions?
3 What's the background and information you're
4 relying on to form those opinions about what you
5 just told us?

6 A. Okay. So all of the internal
7 documents -- excuse me -- that I reviewed, and
8 deposition testimony particularly from medical
9 affairs, since that -- their input would fall
10 within my area of expertise in terms of their
11 knowledge and background.

12 Q. Do you have familiarity with the
13 information that was available to and known by
14 Ethicon at the time that the warnings were
15 initially given and what was available even up to
16 the date of Mrs. Budke's surgery?

17 A. Yes.

18 Q. Okay. Now, starting with the IFU, I want
19 to ask you a couple questions about the IFU.

20 There's a statement regarding
21 bidirectional elasticity allowing adaptation to
22 the body's stresses.

23 Are you familiar with that statement?

24 A. Yes.

25 Q. Can you tell the jury your opinion as to

1 **whether or not the information provided in that**
2 **statement is adequate or not?**

3 A. I think if it were true, it would be an
4 important attribute of the mesh; that if it did,
5 in fact, stretch in such a way to allow or adapt
6 to the forces in the pelvis, that would be an
7 important attribute.

8 **Q. Based on your knowledge of the internal**
9 **documents, is there a factual basis for that**
10 **statement in the IFU?**

11 A. No. There is no evidence whatsoever to
12 support that claim.

13 **Q. There's a statement in the IFU that**
14 **animal studies show that implantation of the**
15 **Gynemesh mesh elicits a minimum to slight**
16 **inflammatory reaction which is transient.**

17 Do you have an opinion as to whether or
18 not that is an adequate warning to physicians?

19 A. Yes, I have an opinion.

20 **Q. And please tell the jury your opinion.**

21 A. That is not adequate and not accurate.

22 The inflammatory reaction is not
23 transient. It is chronic. It is not slight to
24 minimal. It can be quite severe in women, in some
25 women, and it's not possible to predict in advance

1 who -- or which women are going to be on the end
2 of the spectrum --

3 MS. JONES: Objection, Your Honor.

4 A. -- experiencing severe --

5 THE COURT: I'm sorry.

6 MS. JONES: I'm sorry. I think
7 this goes beyond the scope of the question at this
8 stage.

9 THE COURT: All right. Yeah.
10 Stop there and just ask a question because she's
11 back kind of preaching to the choir.

12 Q. (By Mr. Slater) Is the inflammatory
13 reaction with the Prolift transient, meaning it's
14 a short time and ends, or is it chronic?

15 A. It is chronic.

16 Q. Was that known to Ethicon from the day
17 the Prolift was launched?

18 A. Yes.

19 Q. Is the inflammatory reaction with the
20 Prolift minimum to slight?

21 A. No, it is not.

22 Q. And in some women, can it be very severe?

23 A. Yes.

24 Q. Was that known to medical affairs in
25 Ethicon right from the beginning?

1 A. Yes.

2 Q. It says in the IFU that the mesh remains
3 soft and pliable. Are you familiar with that
4 statement?

5 A. Yes, I am.

6 Q. Do you have an opinion as to whether that
7 adequately warned physicians?

8 A. No, it does not.

9 Q. And why do you say that?

10 A. Because in use, the soft -- the mesh does
11 not remain soft and pliable.

12 MS. JONES: Objection, Your Honor.
13 I don't think there's qualifications for Dr. Weber
14 to talk about that.

15 THE COURT: Do you want to voir
16 dire on that question? Or not?

17 MS. JONES: I'll cross-examine her
18 on it, but I --

19 THE COURT: All right.

20 Q. (By Mr. Slater) Are you relying, in
21 part, for your answer on deposition testimony of
22 Ethicon medical affairs as to how the mesh behaves
23 in the body?

24 A. Yes.

25 Q. And based on that testimony, what is your

1 **understanding?**

2 A. My --

3 MS. JONES: Objection. Same
4 objection, Your Honor.

5 THE COURT: All right. Go ahead.
6 I'll overrule it for now. Go ahead.

7 **Q. (By Mr. Slater) You can answer.**

8 A. Okay. My understanding is that the mesh
9 does not remain soft and pliable, it becomes
10 encased in scar tissue, and in some women when the
11 inflammatory reaction becomes very severe, then
12 you have the fibrotic bridging and very stiff,
13 hard, firm tissue.

14 **Q. With regard to Mrs. Budke, is there**
15 **significance to that issue in her case?**

16 A. Yes.

17 **Q. Can you explain that?**

18 A. Yes. Based on Dr. Simpson's medical
19 records, she described palpation of the anterior
20 vagina where the Prolift mesh had been placed,
21 where the mesh was palpable, which means she could
22 feel it, and that's not normal under the
23 circumstances.

24 And then later, when she was in surgery
25 in January of 2009, Dr. Simpson described

1 concentric stricturing of the vagina, and what
2 that means is that in normal anatomy, the vagina
3 has kind of an "H" shape, so the bar across the
4 middle would be the vaginal walls, and then the
5 "H" -- the arms of the "H" are the supports that
6 ordinarily attach the vagina to the pelvic
7 sidewall. And I'm just referring anteriorly,
8 because that's what Mrs. Budke had was the
9 anterior Prolift.

10 So instead of that "H" kind of shape, she
11 had this concentric stricturing, which was because
12 of the Prolift mesh contraction. So instead of
13 having that -- those arms of support in the "H"
14 analogy that I'm giving you, instead, those were
15 obliterated and scarred so that the top of the
16 vagina, the front wall of -- and towards the top
17 of the vagina were strictured. Scarred down.

18 **Q. And what is your basis for saying that**
19 **there was this concentric stricturing around the**
20 **vagina?**

21 A. That was in Dr. Simpson's operative note.

22 **Q. And for -- for the opinions that you're**
23 **drawing, have you relied on the official medical**
24 **records prepared by Dr. Simpson and other**
25 **physicians?**

1 A. Yes, I have.

2 Q. Is that customary for -- for an expert in
3 your field to do?

4 A. Yes.

5 Q. There's a -- there's a statement in the
6 professional education and GPS sales aids stating
7 that this type of mesh does not potentiate
8 infections. Do you have an opinion as to whether
9 those statements adequately inform physicians,
10 including Dr. Simpson, of the risk of infection
11 potentiation?

12 A. Yes, I have an opinion.

13 Q. What is your opinion?

14 A. My opinion is that that's not an adequate
15 characterization of the mesh itself, and in fact
16 was contradicted, the information in the marketing
17 material in the professional education where the
18 mesh did not potentiate infection. In other
19 words, it did not make it easier for the infection
20 to get settled in and -- and -- or -- and magnify
21 the infection. That's what "potentiate" in this
22 context means.

23 And that's contradiction -- excuse me,
24 contradicted by the IFU itself, where it says that
25 infection potentiation is one of the risks of the

1 mesh implantation.

2 Q. In Mrs. Budke's case, was there infection
3 potentiation?

4 A. Yes. Definitely.

5 Q. Now, in the IFU, the word "erosion" and
6 "exposure" appears in the IFU. You're familiar
7 with that?

8 A. Yes.

9 Q. Do you have an opinion as to whether it
10 was adequate to simply mention erosion and
11 exposure in the IFU?

12 A. Yes, I have an opinion.

13 Q. And what's your opinion?

14 A. My opinion is that that was not adequate.

15 Q. Why do you say that?

16 A. That didn't describe the kinds of
17 erosions that some women can develop, the
18 complex --

19 MS. JONES: Objection, Your Honor.

20 THE COURT: Just a minute.

21 MS. JONES: I'm going to object,
22 in that I do not believe that Missouri law
23 requires what I think Dr. Weber is going to talk
24 about.

25 MR. BALL: Missouri law requires a

1 reference to the risk and it doesn't require
2 details about -- all the details about the risk.

3 THE COURT: All right.

4 MR. SLATER: I thought -- we
5 just -- we're just trying to make sure that the
6 basis of the doctor's opinion is understood.

7 THE COURT: Okay. Just get it
8 across there and don't dwell on it, then --

9 MR. SLATER: Okay.

10 THE COURT: -- because I don't
11 want to step on the case law on it.

12 Q. (By Mr. Slater) Okay. The risk of
13 erosion, can you describe what the risk of erosion
14 is based on what you've seen not only in the
15 medical literature but also the internal documents
16 of Ethicon as to what they knew and have admitted
17 they knew from day one?

18 A. Yes. That mesh erosion can be associated
19 with infection, abscess formation, sinus tract
20 formation, fistula formation. These are all some
21 of the clinical consequences that can occur, once
22 mesh erosion has occurred.

23 Q. What is a complex mesh erosion or a
24 complex recurrent mesh erosion?

25 A. A complex recurrent mesh erosion is one

1 that is very difficult to treat.

2 In that kind of a situation, a woman may
3 require several surgeries where portions of the
4 mesh are excised and the -- and the vaginal skin
5 can be closed again but the erosion comes back.

6 This often occurs in the setting of
7 infection, and that's what Mrs. Budke experienced
8 as well, where she had the mesh erosion leading up
9 to her surgeries in January and then developed
10 more mesh erosions in March that then required
11 another surgery to try to excise.

12 Q. Was that, in your opinion, adequately
13 warned of?

14 A. No, not at all.

15 Q. Was that adequately warned of in any of
16 the documents we've listed?

17 A. No.

18 Q. That would be the IFU, the patient
19 brochure, the sales aid, the professional
20 education deck?

21 A. Correct.

22 Q. Did Ethicon warn of whether or not there
23 would be patients that could not be -- safely and
24 effectively have their mesh complications treated?

25 A. No.

1 **Q. Do you have an opinion as to whether that**
2 **was necessary?**

3 A. Yes, I have an opinion.

4 **Q. What is your opinion?**

5 A. My opinion is that was definitely
6 necessary. That's one of the most difficult
7 problems to treat.

8 **Q. And was that adequately warned of in any**
9 **of those documents?**

10 A. No.

11 **Q. It mentions in the IFU implant --**
12 **scarring that leads to implant contraction.**

13 Do you have an opinion as to whether that
14 **was an adequate warning of the full scope of the**
15 **risk of contraction?**

16 A. Yes, I have an opinion.

17 **Q. And what is that?**

18 A. The opinion is that that was completely
19 inadequate, and on -- based on my review of
20 internal Ethicon documents where it stated that
21 the consequences of mesh contraction are vaginal
22 anatomic distortion, scar plating, fibrosis, and
23 that this is a very difficult problem to treat.

24 **Q. We've talked about this document**
25 **previously. It's PLT0062. Are you -- are you**

1 familiar with this journal article?

2 A. Yes.

3 Q. And who are the authors of this article?

4 A. The authors are the TVM group -- they
5 label themselves as such -- with nine authors,
6 nine French authors listed.

7 Q. When was that published?

8 A. This was published in November 2004.

9 Q. And from that article, do you have an
10 understanding as to who -- which women were
11 intended for the TVM, the Prolift procedure, in
12 terms of the severity of prolapse?

13 A. The intention was --

14 MS. JONES: Objection, Your Honor.

15 THE COURT: Yes.

16 MS. JONES: I object to the form
17 of the question, the way it's asked.

18 THE COURT: Okay. Can you
19 rephrase it?

20 Q. (By Mr. Slater) Do you have an
21 understanding, from reading this literature by the
22 inventors of the Prolift, as to what level of
23 prolapse the Prolift procedure was intended for?

24 MS. JONES: Objection, Your Honor.

25 That's -- this is the early TVM --

1 Well, I object to the form of the
2 question, the question as formed, as it relates to
3 that article.

4 THE COURT: Well, I'll let you go
5 ahead and ask it, with the understanding that this
6 was written back at the beginning of time.

7 MR. SLATER: November 2004, three
8 months before the -- four months before the
9 product was on the market, Your Honor.

10 THE COURT: All right.

11 Q. (By Mr. Slater) And what's your
12 understanding?

13 A. I'm sorry. Could you repeat the
14 question?

15 Q. Sure.

16 What is your understanding, based on the
17 article, as to what women were intended for the
18 Prolift procedure, based on what the TVM group
19 published in November 2004 in terms of stage of
20 prolapse?

21 MR. BALL: Object to the
22 relevance, Your Honor. The question is what
23 Ethicon intended, not some French doctor group,
24 and it's irrelevant.

25 THE COURT: What do you say about

1 that?

2 MR. SLATER: I say they invented
3 it, they were paid consultants for the company,
4 they were the TVM investigators, they invented the
5 procedure, and the testimony from Dr. Arnaud was
6 that the company was in close contact with them
7 and held Cosson up as one of the foremost experts
8 in the world with the use of mesh and was
9 consulting with the company --

10 MR. BALL: I think that's a little
11 lengthy --

12 MR. SLATER: -- at all times and
13 was the inventor.

14 MR. BALL: -- that's a little
15 lengthy speech, Your Honor.

16 THE COURT: Well, ask one question
17 about it and then let's go on. Okay?

18 Q. (By Mr. Slater) Do you have an
19 understanding as to what stage of prolapse the TVM
20 group intended the Prolift for?

21 A. Yes.

22 Q. What?

23 A. The TVM group intended the Prolift to be
24 used for the most severe stages of prolapse.
25 Stage 3 and 4.

1 Q. Did Mrs. Budke fall into that category?

2 A. No, she did not.

3 Q. I'm going to give you P1664 and let me
4 just get situated and ask a question.

5 This is a document dated May 15, 2006,
6 about two years before Mrs. Budke's surgery?

7 A. Yes.

8 Q. And it's a document you're familiar with?

9 A. Yes.

10 Q. And rely on, in part, for your opinions?

11 A. Yes.

12 Q. And what I'd like to do, if we could, is
13 turn in this PowerPoint to Page 8.

14 A. Okay.

15 Q. And if you look in the upper left corner,
16 does this official Ethicon document state the
17 patient profile in terms of what stage of prolapse
18 the Prolift was intended for?

19 A. Yes, it does.

20 Q. What does it say?

21 A. It says, "Patient Profile, Stage 3 and
22 4."

23 Q. Did Ethicon ever warn doctors that this
24 device and this system was intended for Stage 3
25 and 4 prolapse?

1 A. No, never.

2 Q. Are you familiar with the testimony of
3 Price St. Hilaire and Paul Parisi consistent with
4 what you've just told us?

5 A. Yes.

6 Q. I'm done with that document.
7 Let's talk about the Prolift patient
8 brochure a little bit. You're familiar with that
9 document, correct?

10 A. Yes.

11 Q. I want to ask you about a few statements
12 in it, to understand whether they're adequate or
13 not, in your opinion.

14 In the Prolift patient brochure, it says,
15 "Soft synthetic mesh specially designed for
16 placement through the vagina."

17 Do you have an opinion as to whether that
18 is an adequate warning to physicians regarding the
19 characteristics and properties of the Prolift?

20 A. Yes, I have an opinion.

21 Q. And what's your opinion?

22 A. My opinion is that it's not adequate.

23 Q. And why is that?

24 A. It's not soft, as we already discussed.

25 It is synthetic.

1 It was not specially designed for use in
2 the vagina. This is the exact same mesh as
3 Prolene Soft, which is a hernia mesh.

4 **Q. It says in the patient brochure that**
5 **complications with the Prolift are rare.**

6 Do you have an opinion as to whether that
7 provided adequate warning to physicians as to the
8 complication rates they could expect with their
9 patients?

10 A. Yes, I have an opinion.

11 **Q. What's your opinion?**

12 A. My opinion is that the claim that
13 complications are rare is very inaccurate.

14 **Q. Why do you say that?**

15 A. Because of my review of all of the
16 Ethicon internal documents, their studies, my
17 independent analysis of their studies, the medical
18 literature that's been published, in no way could
19 complications be considered rare, caused by the
20 Prolift system.

21 **Q. It says that there's a small risk of mesh**
22 **material becoming exposed into the vaginal canal.**

23 Do you have an opinion as to whether that
24 adequately warned physicians regarding the risk of
25 mesh being exposed into the vaginal canal?

1 A. Yes, I have an opinion.

2 Q. What is your opinion?

3 A. My opinion is that that is not an
4 adequate characterization of how frequent mesh
5 erosion occurs.

6 Q. And what's the basis for that?

7 A. The basis for that is, again, as I just
8 mentioned, all of those things I've reviewed, and
9 even Ethicon concedes that the typical mesh
10 erosion rate is 10%.

11 I think 1 in 10 people cannot be
12 characterized fairly as a small chance.

13 Q. In medicine, you practiced as a physician
14 for many years, ran studies, categorized
15 complications. Is that -- is that part of the
16 basis for your opinion?

17 A. Yes.

18 Q. It says in the patient brochure on
19 Page 13, it's appropriate for most patients.

20 Do you have an opinion as to whether that
21 adequately warned physicians as to what women
22 should be operated on with this system?

23 A. Yes, I have an opinion.

24 Q. And what's that opinion?

25 A. The opinion is that that is an inaccurate

1 characterization of appropriate patient selection
2 for the Prolift procedure.

3 Q. You testified a few moments ago about
4 Stage 3 and 4. Is that a factor in that opinion
5 as well?

6 A. Yes.

7 Q. Now, before Mrs. Budke's surgery --
8 before it -- had Ethicon made a corporate decision
9 to make changes to the patient brochure warnings?

10 A. Yes.

11 Q. Before the surgery?

12 A. Yes.

13 Q. Did they inform Dr. Simpson that they
14 were changing the warnings in the patient brochure
15 when that decision was made before the surgery?
16 Did they tell her that in any way?

17 MR. BALL: Your Honor, we need to
18 approach the bench.

19 THE COURT: All right. Yeah. I
20 knew that was coming.

21 (Counsel approached the bench and
22 the following proceedings were held outside the
23 hearing of the jury:)

24 MR. BALL: You've already made a
25 ruling, Your Honor --

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1 THE COURT: On that.

2 MR. BALL: -- that changes that
3 occurred afterwards, that the changes in the
4 warnings are not admissible.

5 MR. SLATER: I wasn't asking about
6 changes made afterwards.

7 MR. BALL: He's --

8 MR. SLATER: I'm asking about
9 decisions -- I'm sorry, Dan. I'm sorry.

10 THE COURT: The decision may have
11 been made but it wasn't published. It wasn't out.

12 MR. BALL: Right. It's unfairly
13 prejudicial to enter into evidence the fact the
14 warnings were changed afterwards, even if the -- a
15 decision was headed in that direction beforehand.

16 THE COURT: I'll leave it like it
17 is now, but I'll give you warning: Don't do any
18 more of that.

19 MR. SLATER: And I don't want to
20 violate a ruling so just so you know what I'm
21 doing, Your Honor, I'm not going to ask if they
22 eventually changed the warnings, but I think the
23 fact that they had acknowledged internally the
24 warnings --

25 THE COURT: You just asked her

1 that.

2 MR. SLATER: Yeah. It was
3 objected to so I don't know that she answered the
4 question.

5 MR. BALL: I don't think there
6 should be any reference that says anything about
7 changing the warnings because there's not going to
8 be anything like that because that's within the
9 Court's ruling.

10 MR. SLATER: I thought Your
11 Honor -- and I respect the rulings -- to say don't
12 bring out that the warnings got changed later and
13 we're not going to bring that out, but the fact
14 that internally the company acknowledged that the
15 warnings, they didn't have support for what they
16 were saying and they needed to change a bunch of
17 things, shouldn't we be able to tell that to --
18 that's a punitive damage issue. I mean, they knew
19 the warnings were wrong and they had information
20 that was untrue and didn't tell the doctor.

21 MR. BALL: He's already -- he's
22 actually done pretty well. He said what was
23 inadequate about it and the basis for it --

24 THE COURT: Yeah.

25 MR. BALL: -- and this is now

1 getting into subsequent changes that should not be
2 allowed.

3 THE COURT: Well --

4 MR. BERGMANIS: Lucente's study
5 was ongoing so it's fair to ask whether or not
6 there were any changes --

7 MR. SLATER: I'm not asking about
8 Lucente's study.

9 MR. BERGMANIS: I understand that.

10 THE COURT: Here's the thing. My
11 ruling's going to stand on the post-remedial
12 action, so let's just get out of it and talk about
13 something else.

14 MR. BALL: Thank you.

15 (The proceedings returned to open
16 court.)

17 Q. (By Mr. Slater) Let me try to ask the
18 question a little bit differently.

19 Before Mrs. Budke's surgery, did Ethicon
20 internally believe that the warnings and
21 information in the patient brochure were accurate
22 or not?

23 MS. JONES: Objection, Your Honor.

24 THE COURT: Sustained.

25 MS. JONES: State of mind.

1 Q. (By Mr. Slater) With regard --

2 THE COURT: That goes to state of
3 mind, and that's -- I don't know what their state
4 of mind was.

5 Q. (By Mr. Slater) Before Mrs. Budke's
6 surgery, have you seen documents indicating
7 whether or not Ethicon had made decisions as to
8 whether or not the warnings and information in the
9 patient brochure were accurate or not?

10 MR. BALL: Your Honor, you have
11 already ruled on this. He's asking the question
12 three times now in an effort to try and avoid
13 the -- Your Honor's rulings.

14 THE COURT: Let's move on.

15 Q. (By Mr. Slater) With regard to the IFU,
16 was Ethicon -- based on documents you've seen, is
17 it documented whether or not Ethicon was aware of
18 what you told us about bidirectional elasticity?

19 A. Yes.

20 Q. And is that a portion of your -- the
21 basis for your opinion?

22 A. Yes.

23 Q. And with regard to all the warnings and
24 information -- rephrase.

25 With regard to the IFU, patient brochure,

1 the GPS sales aid, professional education
2 PowerPoint from 2005, is it your opinion that they
3 failed to adequately warn physicians, including
4 Dr. Simpson?

5 A. Yes.

6 Q. What we're going to do now, Doctor, is
7 we're going to turn and we're going to speak about
8 Joan Budke. Okay?

9 A. Yes.

10 Q. And the first thing I want to do is
11 promise you that I'm not going to put a bunch of
12 medical records, all the records in front of you,
13 but I'm going to ask you to do me a favor for the
14 Court and for efficiency's sake.

15 We have a pile of records here in front
16 of you --

17 A. Yes.

18 Q. -- and we've been through those and --
19 been through those with you, and I just want to
20 ask you: Those are the records from -- all the
21 way from April 2008 plus Dr. Simpson's,
22 Dr. Griswald's records, Dr. Adkins, and every
23 hospitalization all the way through August 5,
24 2009.

25 Have you read every single one of those

1 records?

2 A. Yes, I have.

3 Q. Do those records form, at least in part,
4 the basis for the opinions you're going to offer
5 regarding what happened with Mrs. Budke and her
6 health and -- and what happened to her physically?

7 A. Yes.

8 Q. And are those records important to you in
9 forming your opinions and something that you
10 relied upon?

11 A. Yes.

12 Q. Would you briefly tell the jury about
13 Mrs. Budke and the surgery she had on April 28,
14 2008?

15 In the interest of time, we're going to
16 kind of be in a bit of a summary fashion and then
17 we're going to pick and choose some things to talk
18 about in detail because it deserves to be talked
19 about and I'd like to ask you if you can start
20 that.

21 A. Yes.

22 So Mrs. Budke, as Dr. Simpson recorded in
23 the hospital chart, had a first- to second-degree
24 cystocele. We talked about that before.

25 She also had some urinary issues, so

1 Dr. Simpson was planning some other procedures to
2 address those.

3 And on April 28th, Dr. Simpson performed
4 the anterior Prolift procedure with some other
5 procedures designed to address her urinary
6 problems by Dr. Simpson.

7 She was initially well after her surgery.

8 At her first postoperative visit, as I
9 mentioned earlier, Dr. Simpson was able to palpate
10 the mesh. It was tender. Dr. Simpson wasn't sure
11 if there was possibly an infection starting, so
12 she treated her with antibiotics by mouth, and
13 then saw Mrs. Simpson back in another month, and
14 at that time a mesh erosion had developed.

15 And then she saw her again a couple of
16 months later. The mesh erosion was persistent.

17 She was seen again in the beginning of
18 January by Dr. Simpson's nurse practitioner and
19 the mesh erosion was still present.

20 **Q. Let me stop you there.**

21 A. Okay.

22 **Q. Do you have an opinion as to what's**
23 **caused the mesh erosion that you've talked about?**

24 A. The cause of mesh erosion is not
25 completely understood.

1 It's understood that the -- the mesh
2 causes the inflammatory reaction that we've talked
3 about, cell damage, cell death, tissue damage, and
4 then with other contributing factors, it is --
5 results in the Prolift mesh eroding through the
6 vaginal wall and becoming visible.

7 **Q. Now, as Mrs. Budke now went into early**
8 **2009, what was her condition?**

9 A. Yes. At the time she saw the nurse
10 practitioner, she was well.

11 In the course of the next couple of
12 weeks, into the middle/end of January, she became
13 critically ill. This is when the abscess
14 manifested itself, and as we talked about earlier,
15 the inflammation took up so much space to the
16 extent that the ureters, the tubes from the kidney
17 to the bladder, were blocked, and when that
18 happens, the urine has nowhere to go and those
19 things in the urine that your body's trying to get
20 rid of get reabsorbed and go back in your
21 circulation and that makes the kidneys fail. So
22 she was in acute kidney failure.

23 And at that point, she was brought to the
24 hospital and the first operation was performed.

25 **Q. Now, this was in January 23, 2009?**

1 A. Yes.

2 Q. What I'd like to do now is: Have you
3 also viewed the imaging studies? The CAT scans,
4 the x-rays, and these other studies that were
5 actually performed on Mrs. Budke?

6 A. Yes, I have.

7 Q. And do those form a basis for your
8 opinions as well?

9 A. Yes.

10 Q. Okay. What I'd like to do is we have the
11 scout film for the CAT scan of January 22, 2009.
12 I'd like to put that up, please.

13 And while we're doing that, Dr. Weber, we
14 under- -- I just want you to understand
15 Dr. Simpson's testified and Dr. Dixon will be
16 testifying, so that's why we're skipping along a
17 little bit, because no need to repeat everything.

18 A. Right.

19 Q. Will you tell the jury what they see
20 here?

21 A. Yes. Could I have the laser pointer
22 back, please? I gave it back.

23 So this is what's called a scout film, so
24 this is something that's taken before an imaging
25 test, like a CAT scan. And we'll see some of the

1 images from the CAT scan, but I just wanted to put
2 this up to orient you.

3 So in the CAT scan machine, Mrs. Budke is
4 lying on her back, and this image just shows, as
5 you can see from the bottom part of the lung -- I
6 just want to use my little pointer.

7 Okay. The bottom parts of the lungs here
8 (indicating). There's the heart (indicating).
9 The lower ribs, you can see.

10 Coming down into the abdomen, those
11 (indicating) are gas in the large intestine where
12 it belongs. That's healthy.

13 And then of course the bones of the
14 pelvis, the spinal column, and then the hip here
15 (indicating), the top of the femur, the thighbone,
16 on each side.

17 And for -- what a CAT scan does then is
18 take slices, like as if it were, you know, through
19 your body like through and through, and we're
20 going to look at a couple of those pictures.

21 **Q. Are you ready for the next image?**

22 A. Yes.

23 **Q. And this is from the January 22, 2009 CAT**
24 **scan?**

25 A. Yes.

1 Q. Okay. Go to the next one, please.

2 A. Okay. So let me orient you here again.

3 So she's lying on her back. The front of
4 her is up here (indicating). The back of her is
5 here (indicating). And here (indicating) you can
6 see bone highlights very clearly in white.

7 So this (indicating) is just the bottom
8 of the tailbone, okay?

9 Here (indicating) you can see her hip
10 bones on the right and on the left.

11 Back here (indicating) is the rectum.
12 And you can see a -- the dark spaces, at least
13 some of them, are gas pockets, so gas in the
14 rectum is perfectly normal, as we all know.

15 The front of her. So this (indicating)
16 would be the front of her abdominal wall.

17 And here (indicating), this -- this
18 larger gray circle is the Foley balloon inside the
19 bladder, and then that smaller dark circle inside
20 is the Foley catheter itself.

21 The way the Foley catheter works, just
22 since you're looking at it here, the catheter is
23 inserted through the urethra into the bladder and
24 then the balloon is inflated with fluid, saline,
25 so that that keeps the catheter inside the

1 bladder. Otherwise, it would just slip out. But
2 now with the balloon, the balloon is big enough it
3 can't slip down the urethra and fall out, so that
4 keeps the catheter in the bladder.

5 And then you can see this layer of tissue
6 (indicating) around the Foley balloon, and that's
7 the bladder wall. The front part of the bladder
8 wall. And you don't see any urine in the bladder,
9 of course, because the catheter is there draining
10 the urine out, so there's no fluid-filled space
11 that would be the bladder.

12 **Q. And what's the significance of the air**
13 **pocket within that area? What's that telling you?**

14 A. This one (indicating)?

15 **Q. Yes.**

16 A. Okay. That's what I'm getting to. Yes.

17 So this area (indicating), this would be
18 encompassing the front wall of the vagina, and
19 this whole area here (indicating) is the pelvic
20 abscess.

21 Now, mesh is not something that can be
22 seen on CT scan, but we know, just from her
23 history, that somewhere in this red circle
24 (indicating) is the Prolift mesh implant, that --
25 that central body that we saw earlier.

1 And this (indicating), the black stuff,
2 is an air pocket within the abscess, and all this
3 (indicating) is the inflammatory tissue, pus,
4 which is basically white blood cells, bacteria,
5 the body's reaction to trying to respond to this
6 very significant infection.

7 And so the air pocket inside is a
8 characteristic finding of an abscess which,
9 especially in the pelvis, is almost always a
10 combination of different bacteria, which is what
11 we call a polymicrobial infection. So "poly"
12 means many; "microbial," microbes, bacteria,
13 yeast, any kind of microorganism. So many
14 different organisms.

15 And there are certain types of organisms
16 that just produce gas as part of their metabolism,
17 and so that's what's seen here in this very large
18 inflammatory mass between the bladder and the
19 rectum.

20 **Q. We've heard a little from Dr. Simpson**
21 **about the surgery she performed with Dr. Dixon, so**
22 **I would just ask, so that we have a basis when we**
23 **go forward and a little bit of foundation and, you**
24 **know, pretty quick, what was done here.**

25 **We're going to move ahead -- we have a**

1 lot to cover and we're going to move ahead to the
2 parts we haven't heard yet --

3 A. Okay.

4 Q. -- but just to situate ourselves, what
5 happened in this surgery on the 23rd?

6 A. Okay. So what Dr. Simpson did was put an
7 incision in the front wall of the vagina, similar
8 almost to what is the very beginning step of doing
9 a repair procedure.

10 So putting an incision in the front wall
11 of the vagina, and there she encountered this
12 pelvic abscess -- and she talked to you a little
13 bit about that, I imagine -- pus; necrotic tissue,
14 which is basically dead tissue; damaged tissue;
15 inflammation; and then the mesh itself, which was
16 encased in -- in all of this inflammation and
17 infection.

18 Q. After that surgery, going forward, can
19 you take us forward a little bit and we'll walk
20 our way up to March, if we could.

21 A. Okay. So after this surgery where part
22 of the mesh, of the anterior Prolift mesh implant,
23 was removed, the following week another operation
24 was done where more mesh was not removed but more
25 debridement, which is the surgical term for

1 basically cleaning out the infected, necrotic,
2 dead, unhealthy tissue; irrigation, which is just
3 rinsing and rinsing and rinsing to try to flush
4 out as much of the material -- you know, the
5 tissue -- the tissue that wasn't surviving and
6 healthy, just to get that out of the way and give
7 a better chance, hopefully, of having this heal.

8 And then she was released from the
9 hospital --

10 Oh, and -- well, should I mention
11 Dr. Dixon and the ureters?

12 **Q. Yes. In both January 23rd and at the end**
13 **of the month -- I think it was the 30th or the**
14 **29th -- was he able to be successful with what he**
15 **wanted to do as a urologist?**

16 A. No. No. The ureters were blocked, and
17 so what was -- what he wanted to do was to be able
18 to pass a stent from the bladder into the opening
19 of the ureter and then up to the kidney, to
20 provide a way for the urine to get out until this
21 inflammation settled down and the ureters could be
22 opened by themselves.

23 But there was so much inflammation, not
24 only could he not pass a stent on either side, he
25 couldn't even find the openings of the ureters

1 into the bladder at either operation, one -- you
2 know, the two operations about a week apart.

3 Q. And Dr. Dixon then took Mrs. Budke to
4 another hospital to have what done?

5 A. Right.

6 So he recommended that they go to a
7 hospital that had the facilities to perform a
8 procedure where the stents are placed in not from
9 the bladder but from the -- from the kidneys
10 themselves. Put the -- put the stent in through
11 the back of the wall into the kidney in that way,
12 and then feed the ureter -- excuse me, feed the
13 ureter -- sheesh -- feed the stent down the ureter
14 to where it could be in the bladder.

15 So that was successfully accomplished at
16 a different hospital.

17 But while Mrs. Budke was there, the
18 doctor noticed that she had a clot in her kidney,
19 a blood clot that he didn't think was really
20 accounted for by the procedure itself. It seemed
21 to him that there was more of a blood clot there
22 than could be explained just by having the -- the
23 stent being passed at that point, and he decided
24 to bring her into the hospital, because this was
25 otherwise planned as an outpatient procedure where

1 she came in and had it done and then went back
2 home. He instead decided to keep her and do some
3 more tests to try to find out what was wrong.

4 Q. And what I'd like to do now is we want to
5 pull up P1873, the February 5, 2009 medical chart.
6 Specifically, it's Bates stamped Page 91, which is
7 the -- looks like the admitting consult note with
8 Dr. Schultz. Now, I want to just draw your
9 attention to a couple things.

10 First of all, the reason for
11 consultation, let's see what Dr. Schultz wrote.

12 "I was asked to see Mrs. Budke both
13 personally by Dr. Jill Oberle and by order in the
14 chart regarding the possibility of metastatic
15 cancer of the lungs in this 76-year-old woman
16 admitted with pelvic floor infection with
17 bilateral ureteral obstruction."

18 What was happening that led an oncologist
19 to be involved and looking at -- for potentially
20 cancer spreading into the lungs at this point?

21 A. Yes.

22 So when she was admitted to the hospital
23 in January, she had the CT scan that we looked at
24 that showed just the bottom parts of her lungs,
25 and the radiologists saw a couple of nodules.

1 And so the concern was there was
2 something going on in her lungs, and the thought
3 was, "Okay, let's get her through this first week
4 of addressing the pelvic abscess directly and look
5 into this lung problem a little bit later."

6 So then when she went to Missouri Baptist
7 Hospital and had the stents placed and then had
8 extra work -- you know, extra testing being done,
9 she had a full chest CT and chest x-ray that
10 showed nodules that the doctors were initially
11 suspicious could be related to metastatic disease.

12 And what that means is that if there's
13 cancer somewhere else in the body and it gets into
14 the bloodstream, then it can land in the lungs and
15 continue to grow and be a problem like cancer is.

16 **Q. Now, throughout the hospitalizations and**
17 **the rest of what went on in 2009, I just want to**
18 **take care of one thing.**

19 **Mrs. Budke never was diagnosed with**
20 **cancer, correct?**

21 A. That's correct.

22 **Q. It was -- it was thought that she may**
23 **have it at different times, but she did not have**
24 **cancer. Correct?**

25 A. That's correct.

1 Q. Okay. Now, down a little further down,
2 there is a paragraph just above the past medical
3 history -- we'll pull that up and I want to ask
4 you a quick question about that -- where it talks
5 about Mrs. Budke having some -- Joan having some
6 discomfort in her chest, going to the local
7 doctor, and it says that the chest image was
8 performed showing the presence of multiple small
9 nodules, as you said, questionable for metastatic
10 disease, with the differential diagnosis in this
11 patient also including septic emboli.

12 And what does that mean?

13 A. Okay. So as doctors, when we have
14 someone come in with a problem, we construct a
15 differential diagnosis, which is really basically
16 a list of what could be wrong with this person and
17 in some order -- not fixed in stone but just in
18 our minds in some kind of order as far as what's
19 likely -- what's more likely, less likely, and
20 have that list of the things that could be wrong
21 with someone.

22 So we've already talked about the
23 possibility of metastatic cancer, which turned out
24 not to be the case but it was certainly a concern,
25 especially in the early part of Mrs. Budke's

1 evaluation, and then the septic emboli.

2 So septic emboli are a -- an embolus is
3 just something that travels to the lungs.
4 "Septic" means that the embolus itself is carrying
5 an infection.

6 And so a thrombus, which --

7 **Q. What is that?**

8 **A.** An embolus.

9 So a thrombus is a blood clot. An
10 embolus is a little less specific. It basically
11 means anything that travels to the lung.

12 So a thrombus is a little more specific
13 because it's a blood clot that travels to the
14 lungs, but the -- so the embolus can be a blood
15 clot, it could be purely infectious material, you
16 know, a pack of white blood cells, bacteria, cell
17 products, that kind of a thing, that eventually --
18 because they get into the circulation, they
19 eventually get to the lungs because that's just
20 the way the body's circulation works.

21 **Q. And going forward, I just -- I want to**
22 **ask you one question. Then we're going to go**
23 **forward.**

24 **Do you have an opinion, to a reasonable**
25 **degree of medical certainty, ultimately as to what**

1 **caused those nodules in the lungs?**

2 A. Yes.

3 MR. BALL: Your Honor, I will
4 object now to lack of qualifications for a
5 gynecologist to talk about lung issues like this.

6 **Q. (By Mr. Slater) Is it part of your**
7 **medical training --**

8 MR. BALL: May we approach the
9 bench, Your Honor?

10 THE COURT: Yes, you may.

11 (Counsel approached the bench and
12 the following proceedings were held outside the
13 hearing of the jury:)

14 MR. BALL: Mr. Slater has an
15 infectious disease expert that he has disclosed.
16 He has a lung pathologist expert he has disclosed.
17 He has a radiologist he has disclosed. And he
18 should not have an unlicensed,
19 no-longer-practicing-medicine gynecologist talking
20 about lung disease and the causes of lung disease
21 and the causes of septic emboli in the lungs.
22 That is beyond her qualifications and it should
23 not be allowed in this court.

24 And there are numerous Missouri cases
25 saying that just because somebody's a doctor and

1 learned about something in medical school doesn't
2 make them an expert sufficient to -- under the
3 Missouri statute and the Missouri law to state an
4 opinion about everything that's medicine.

5 MR. BERGMANIS: He was in the
6 process of laying his opinion, the foundation.
7 You objected before he got done.

8 MR. BALL: That's right because I
9 didn't want --

10 MR. BERGMANIS: But how will you
11 know if he's going to even get there?

12 MR. BALL: Because I didn't want
13 to blurt out rules here. There's been a little
14 bit of blurting out going on here today.

15 MR. BERGMANIS: He's not finished.

16 MR. BALL: It doesn't matter. I
17 don't -- there's no question he can ask that can
18 turn an unlicensed doctor who no longer practices
19 medicine into a lung specialist.

20 THE COURT: Well, if this is all
21 he had to depend on, if this was the only doctor
22 he had, I'd feel really sympathetic about letting
23 her opine to something, but I don't in this case
24 because a lot of what you stated is true, and then
25 secondly, I went to law school like the rest of

1 you. I took a course in admiralty but I'm not an
2 admiralty lawyer and I shouldn't opine on what
3 happened to a boat out in the ocean any more than
4 Jack and Jill should have dropped the bucket.

5 But anyway, no, I'm not going to let you
6 have her opine to that.

7 MR. SLATER: Could I offer --

8 MR. BERGMANIS: Could we try to
9 lay the foundation?

10 MR. BALL: That's outside the --

11 (Court reporter interruption.)

12 THE COURT: Whoa, whoa, whoa. I
13 don't know whether he will or not, but I'm going
14 to give him a chance to make a record on this.
15 But it's out.

16 Go on and make a record.

17 MR. SLATER: Okay. Judge, in
18 Missouri, it's well -- in Missouri, under
19 Section 490.065, to be qualified as an expert, a
20 witness must have knowledge, skill, experience,
21 training, or education so that his or her opinion
22 will probably aid the trier of fact.

23 The law to allow someone to be qualified
24 in Missouri is a very open-door type of one and we
25 all know that. It says that the experience and

1 competence of a medical expert goes to the weight,
2 not the admissibility of her -- his or her
3 testimony, and in fact, when an expert from a
4 particular profession is called to testify, it is
5 not normally required that he be a specialist in a
6 particular branch of that profession.

7 I'm reading from the case of MacDonald
8 v. Sheets, and it's basically citing to these
9 general propositions from the Missouri Supreme
10 Court.

11 MR. BALL: Can I see the case,
12 please?

13 MR. SLATER: Dr. Weber is a board
14 certified physician who actually functioned at the
15 very highest levels of medicine and academic
16 medicine in the United States of America for a
17 long time.

18 Dr. Weber knows what all of the medical
19 issues in this case are. Now, if they think she
20 doesn't know enough to be persuasive to the jury,
21 they can cross-examine her on the weight of the
22 evidence. The defense has a urologist named
23 Dr. Elizabeth Kavalier who offered all the same
24 opinions on all the same areas, and she is just a
25 urologist, and --

1 THE COURT: I didn't know you used
2 a urologist to talk about her lung problems.

3 MR. BALL: Who used that?

4 MR. SLATER: You did.
5 Dr. Kavalier.

6 MR. BALL: We haven't tendered
7 that at all. We have not tendered that.

8 THE COURT: I'll sure give you a
9 chance to jump all over that, but, you know, I
10 don't want -- I don't think I've got a conflict
11 with the Missouri Supreme Court over this but I
12 just -- go ahead.

13 MR. BALL: It's not, it's not.
14 The was a case -- the case he cited from is a case
15 involving dental problems and they had a -- they
16 had a dentist but not an oral surgeon and they had
17 an ENT -- ear, nose, and throat person -- and the
18 doctor said -- the Court essentially said that's
19 close enough. We're way off here.

20 MR. SLATER: The general
21 propositions are well known and the law has been
22 very inviting to allowing people to testify and it
23 goes to the weight.

24 THE COURT: We're close to
25 testifying as to what the ultimate fact of her

1 death was, and I just don't think she's the one to
2 bring that in on.

3 MR. SLATER: She's a physician,
4 Your Honor.

5 THE COURT: I know she is.

6 MR. BALL: She's not a physician
7 any longer.

8 MR. SLATER: Well, she's an M.D.

9 (Court reporter interruption.)

10 THE COURT: Here's the thing. I'm
11 going to sustain the objection, so...

12 MR. BALL: Thank you.

13 (The proceedings returned to open
14 court.)

15 Q. (By Mr. Slater) Okay. Dr. Weber, we're
16 going to skip ahead now to the March 25, 2009
17 hospitalization at University of Missouri --
18 University Hospital. It's Exhibit 1875. And
19 right on top is the operative report. We're going
20 to put that up in front of you and ask you a few
21 questions about that. Okay?

22 A. Yes.

23 Q. If you could, Dr. Weber, are you familiar
24 with this operative report?

25 A. Yes, I am.

1 Q. And would you walk the jury through and
2 explain what was happening with Joan? Tell us
3 what her condition was that led to this operation,
4 please.

5 A. Yes. There we go.

6 So this was a procedure performed by
7 Dr. Neal, and this is just the ordinary format of
8 a dictated operative note pretty standard across
9 all hospitals.

10 She had been in the office with both
11 Dr. Neal and Dr. Hunter. You can see those --

12 MR. BALL: Your Honor, for the
13 record, I would -- excuse me.

14 I would like to interpose an objection.
15 Dr. Neal has given testimony about his own record
16 and his own report, and I believe it's cumulative
17 to have somebody else testify about that, but I'm
18 making that --

19 THE COURT: Well, you know, you --
20 you people have been through this from the get-go,
21 day one. This is all new to me. I sat down here
22 like a goose last Monday and started on it and I
23 don't know about who all you've deposed and
24 everything but I don't need cumulative testimony,
25 if that's what it is.

1 If you've got something in there that's
2 going to be pointed out that Dr. Neal didn't talk
3 about, then fine.

4 MR. SLATER: I think that we're
5 going to lay a foundation for some opinions, and
6 Dr. Neal's was deposed by both parties and I
7 assume that both parties are playing their
8 portions, but I think I need Dr. Weber to at least
9 explain what was happening. Otherwise, there's no
10 context for what she's going to tell the jury.

11 MR. BALL: I'll wait until I hear
12 where we're going before I --

13 THE COURT: Okay. That's good.
14 Yeah. Fair enough.

15 **Q. (By Mr. Slater) Okay. Dr. Weber, please**
16 **tell us what was happening at that point.**

17 A. Okay. So Mrs. Budke had been seen by
18 Dr. Neal and Dr. Hunter. Dr. Neal is a urologist.
19 Dr. Hunter is a gynecologic oncologist, so that's
20 the kind of a doctor who specializes in caring for
21 women with gynecologic cancers and also women who
22 have very difficult surgical problems, because
23 they have an extra amount of surgical experience
24 compared to regular gynecologists.

25 So she had been seen in the office the

1 preceding week by both of these doctors, and they
2 were not able to examine her as fully as they
3 would have liked because she was so uncomfortable.
4 They couldn't really get all the information just
5 from examining her. And there was still the
6 lingering concern that this might represent a
7 cancerous condition and they wanted to check again
8 that that wasn't the case.

9 Also, she had new mesh erosions where the
10 mesh had again eroded through the vaginal wall on
11 both sides, and Dr. Neal was planning to take care
12 of that.

13 **Q. When you say there was a mesh erosion on**
14 **both sides, what are we talking about?**

15 A. So previously, Mrs. Budke's mesh erosion
16 was roughly in the center of the front wall of the
17 vagina and then Dr. Simpson removed a portion of
18 that middle piece, that body of the Prolift mesh
19 implant, and now what Dr. Neal was seeing was mesh
20 erosions out toward the side of the vaginal wall,
21 rather than in the center.

22 **Q. And did the operation actually go**
23 **forward?**

24 A. Yes, it did.

25 **Q. And what occurred during the operation of**

1 **significance to you?**

2 A. Dr. Neal dictated in his operative note
3 that he removed mesh from both sides of the
4 vagina, and like we talked about earlier, because
5 the mesh is in such close proximity to the
6 bladder, and also because of all the inflammation
7 and tissue damage that was going on at the time,
8 Dr. Neal inadvertently made a hole in the
9 bladder -- that's called a cystotomy -- in the
10 course of removing the pieces of mesh that he did
11 remove. And that was repaired.

12 **Q. What I would like to do is provide you an**
13 **exhibit and it's Exhibit 1925. I'd like to put**
14 **that up and ask you to explain to the jury what**
15 **they're looking at, please.**

16 A. Yes.

17 **Q. What is that?**

18 A. So this is the pathological specimen of
19 the mesh that was removed from Mrs. Budke by
20 Dr. Neal on March 25th.

21 **Q. And what is that? What are we seeing**
22 **there?**

23 A. So this is a portion of the mesh itself,
24 and then -- and you can see in certain locations a
25 remnant of the pore shape, and you can also see

1 these little -- these little white strands
2 (indicating).

3 These are fragments of the mesh where the
4 mesh has become thinner, as opposed to the regular
5 thicker strands.

6 And more up here (indicating) you can see
7 where it's shredded, really, for lack of a better
8 term.

9 And then in these red areas (indicating),
10 you can see the fibrotic tissue, the scar tissue
11 that's grown onto the mesh, and it's red because
12 it's so inflammatory and with inflammation,
13 naturally the body is trying to bring extra blood
14 to the area to help fight off the problem, and so
15 there's extra blood vessels, the inflammatory
16 tissue appears very red, and you can see here that
17 it has that appearance as part of the mesh and the
18 scar tissue that's been removed from Mrs. Budke's
19 body.

20 Q. You talked about fibrotic tissue.

21 Is that the bridging fibrosis, the scar
22 plating you talked about earlier?

23 A. Yes.

24 Q. And you spoke earlier about what happens
25 with the arms and the roping and all those things.

1 **Is this a helpful demonstration of the**
2 **results of that?**

3 A. Yes. I believe what this represents is
4 the side edge of that large central implant, the
5 body of the mesh, and then where one of those mesh
6 arms goes off, here you can see -- it's not a
7 complete circle, but you can see this looks
8 semicircular, and here it looks either circular or
9 it's a whole cord of tissue and mesh where the
10 tissue has grown into the mesh, the scar plating,
11 the fibrosis pulling the mesh together, which --
12 mesh contraction that we've talked about.

13 **Q. And this process that you're talking**
14 **about with the mesh, would that have had any**
15 **relationship to the mesh erosions?**

16 A. Yes.

17 **Q. Explain that.**

18 A. So mesh contraction is definitely a
19 predisposing factor for the development of mesh
20 erosion. So while all this intensified
21 inflammatory and foreign body reaction is going
22 on, there is the -- the cell death, tissue damage,
23 and that's another reason how the mesh erodes
24 through to get to -- through the surface of the
25 vaginal wall.

1 Q. Now, what I'd like to do is take a step
2 back to Exhibit 1874 and I'll show you the page to
3 save you a little time.

4 1874, and we're looking for this page.
5 04736. Admission notes.

6 MR. BALL: What is it there, Adam?

7 MR. SLATER: It's an admission
8 note with an impression from a transvaginal
9 ultrasound of the pelvis.

10 MR. BALL: And what is the date?

11 MS. JONES: I'm sorry. Would
12 you --

13 MR. SLATER: It's March 9, 2009, I
14 believe.

15 Q. (By Mr. Slater) Okay. Let's pull up the
16 portion that says "Transvaginal Ultrasound" down
17 through the Paragraph Number 1, and we'll talk
18 about that.

19 MS. JONES: Adam, what -- is that
20 04736 on the bottom?

21 MR. SLATER: Yeah.

22 MS. JONES: Thank you.

23 Q. (By Mr. Slater) Okay. What is this
24 telling us?

25 A. Okay. So the doctors wanted to have an

1 ultrasound done of Mrs. Budke, and the report is
2 described as limited because Mrs. Budke couldn't
3 tolerate the endovaginal exam.

4 As you may know, ultrasounds can be done
5 in many different ways: a surface ultrasound or
6 using a thin probe actually placed in the vagina
7 to look around at the pelvic tissues.

8 Except in this instance, Mrs. Budke was
9 so uncomfortable with having that probe in the
10 vagina, that the ultrasonographer found that the
11 examination was limited. All the information that
12 could normally be obtained wasn't obtainable
13 because Mrs. Budke was too uncomfortable.

14 **Q. And what's the significance of that, in**
15 **terms of the mesh? Is there any connection to**
16 **that?**

17 A. Yes.

18 **Q. And what is that?**

19 A. Well, at this point she's -- she's past
20 the first mesh excision but before the second one,
21 so you still have the same ongoing processes that
22 we've talked about. The inflammatory mass is
23 there. The mesh contraction.

24 You can imagine if the probe is -- is in
25 the vagina and putting any pressure on the -- on

1 the mesh that's contracted, then that would be
2 very uncomfortable because that would put even
3 more pressure on the mesh, and causing Mrs. Budke
4 to be -- to have quite a lot of pain.

5 Q. And this is the condition she was in as
6 she's leading up to this surgery with Dr. Neal?

7 A. Yes.

8 Q. What was her overall medical health, what
9 was her overall condition as she was dealing with
10 this infection in her pelvis and what you've been
11 telling us about? How was she doing?

12 A. Yeah.

13 Before her surgery, she had been quite
14 well.

15 By this time, in the middle of March,
16 she's already starting to -- to weaken. Her
17 appetite is poor. Of course she doesn't feel well
18 so she doesn't feel like eating. She's not
19 getting around because she's in a lot of pain. So
20 she's beginning to lose weight, and as most of you
21 probably know, if you're not using your muscles,
22 they very quickly waste away. So she was
23 beginning to have muscle wasting, deconditioning,
24 which meant basically that her tolerance for any
25 kind of exercise was rapidly diminishing.

1 Q. Now, as we go forward, I'm not going
2 to -- I'm not going to put this up just yet
3 because I want to just move along, but there's a
4 June 5, 2009 hospitalization at DePew [sic]
5 Hospital of St. Louis, and I'd like to ask you a
6 couple questions about some of the language in
7 here.

8 It talks about a vesicovaginal fistula.
9 What is that?

10 MR. BALL: Can you tell us what
11 you're reading from?

12 MR. SLATER: The history and
13 physical on admission, the June 5, 2009 admission.

14 MR. BALL: Thank you.

15 MS. STRAUSS: What Bates is it?

16 MR. SLATER: 691.

17 MR. BALL: Thanks.

18 Q. **(By Mr. Slater) What's a vesicovaginal**
19 **fistula?**

20 A. So a fistula is an abnormal connection
21 between two different organs.

22 So "vesico" is the medical word for
23 bladder; "vaginal," obviously. So an abnormal
24 connection between the bladder and the vagina.
25 And we touched on this just briefly earlier this

1 morning where that means the -- the urine is
2 effectively bypassing the urethra.

3 There's no storage of urine which happens
4 normally when the urethra is closed. The urine is
5 just constantly pouring out the vagina because she
6 has no way of controlling that.

7 **Q. What was the cause, in your opinion, of**
8 **this fistula?**

9 A. There were contributing factors that all
10 led back to the Prolift mesh.

11 The surgeries that she required for the
12 Prolift mesh excision.

13 The ongoing cell death and tissue damage
14 related to the mesh that was left behind.

15 The surgeries that re- -- that were
16 required that introduced their own level of tissue
17 damage, which is unavoidable.

18 Her impaired ability to heal because she
19 was becoming so weakened, malnourished. She
20 wasn't taking in enough calories. She was losing
21 weight.

22 So those -- all those factors contributed
23 to the development of this -- of this huge
24 fistula.

25 **Q. And when we talk about a fistula, it's a**

1 connection between the bladder and the vagina?

2 They actually become connected by essentially an
3 opening?

4 A. Yes.

5 Q. What does that tell us about the
6 condition of her vagina and vaginal tissue at that
7 point?

8 A. That it's -- it's not healthy enough to
9 heal and maintain the normal separation of -- of
10 those two organs.

11 Q. In reading these records, it says that
12 she had a G-tube in place.

13 What is a G-tube?

14 A. So a G-tube is a gastrostomy tube.
15 "Gastro" means stomach.

16 So because she was taking in so few
17 calories on her own, because she had no appetite,
18 losing weight, losing muscle mass, being
19 deconditioned and weakened, her doctors
20 recommended that she have a G-tube placed.

21 And what that is, is a tube that goes
22 from the outside directly into the stomach and
23 pumps liquid food into the stomach.

24 So it -- she was still able to eat, but
25 the -- to try to build her back up and at least to

1 try to keep her from losing even more weight,
2 the -- the idea was to give her supplemental
3 nutrition through this tube in her stomach.

4 **Q. There's mention of a sacral decubitus.**
5 **What does that mean?**

6 A. Yeah. A sacral decubitus is -- you could
7 make a good analogy with a vaginal mesh erosion,
8 actually, without the mesh part.

9 But because she was essentially
10 bed-bound, she was lying in bed. She could once
11 in a while get to a chair but she wasn't up and
12 around in any kind of a normal way. So what
13 happens is, with that unrelenting pressure on the
14 skin, and because she had lost so much weight, she
15 didn't have any protective cushioning of a little
16 fat under the skin right at the bottom of her
17 tailbone. You know, it's kind of a bony
18 prominence there. And that eventually wears away
19 the skin and some of the tissue over the bones,
20 and it never did heal in her. That was present
21 from at least April until the time of her death.

22 And the other problem that undoubtedly
23 contributed to that was the vesicovaginal fistula.
24 Because she had urine pouring out of her all of
25 the time and the wound care people didn't want her

1 to wear briefs because that would, you know,
2 contain the moisture, so instead, she's lying on a
3 pad in her bed that's constantly soaked,
4 incredibly uncomfortable, and, you know, despite
5 their best efforts at wound care to try to get
6 these sacral decubiti to heal, they never did
7 heal.

8 Q. There's a reference to "thrombocytosis
9 likely reactive from infection as well as from
10 multiple chronic stimuli."

11 What is that?

12 A. So "thrombocytosis" is a description of
13 the platelet count.

14 So the platelets are part of the blood
15 cells that circulate in your body, and if you have
16 a scratch, they begin the clotting process to get
17 your cut to stop bleeding and go on to -- to go to
18 the next stages of healing.

19 Now, in Mrs. Budke's case, she had a
20 very, very high platelet count, and that started
21 quite early in her course as far as being
22 abnormally high, and it became even higher, the
23 more sick she became.

24 So why does that happen? The bone marrow
25 was being stimulated because she was anemic. She

1 a low blood count. So the body is telling the
2 bone marrow, "Okay, make more blood cells, make
3 more blood cells," but it made too many platelets.

4 And then the multiple other chronic
5 stimuli that was recorded, in the presence of a
6 chronic infection, the body also responds by
7 making more platelets. The -- the open tissue
8 areas, the sacral decubiti, the mesh erosions, the
9 vesicovaginal fistula, all of those are stimuli
10 that the body responds to by doing things like
11 making more platelets.

12 Q. You mentioned chronic infection. Did
13 Joan have chronic infection?

14 A. Yes.

15 Q. And do you have an opinion as to whether
16 the chronic infection, the fistula, the
17 thrombocytosis, the anemia, the deconditioning,
18 all the things you talked about, whether or not
19 they were caused by the -- started the process,
20 the mesh erosion and the infection?

21 MR. BALL: Object to the form and
22 the foundation.

23 THE COURT: Can you restate it?

24 Q. (By Mr. Slater) What is the cause, in
25 your opinion, of all of the different conditions

1 that we've been talking about: the need for the
2 gastrostomy tube, the thrombocytosis, the
3 deconditioning, the fistula, the decubitus ulcer,
4 all of these things that Joan was having to deal
5 with now in her life?

6 What was the cause, in your opinion?

7 A. None of this would have happened without
8 the Prolift mesh implantation.

9 Q. And why do you say that?

10 A. Because that initiated the cascade.
11 She started with the mesh erosion that
12 became infected, developed this pelvic abscess
13 that blocked her ureters and put her into acute
14 renal failure. She required procedure after
15 procedure to try to address this problem. She had
16 the septic emboli that went to her lungs and she
17 developed a pneumonia --

18 MR. BALL: Your Honor,
19 Your Honor --

20 MS. JONES: Objection. That's --

21 MR. BALL: We just had a ruling
22 on -- may I approach the bench?

23 THE COURT: Yes, you may.

24 (Counsel approached the bench and
25 the following proceedings were held outside the

1 hearing of the jury:)

2 MR. BALL: You know, we just had a
3 ruling about her not talking about the lungs and
4 I'm about ready -- I'm about ready to move for a
5 mistrial on these repeated little jabs at trying
6 to violate the court's orders. That was
7 inappropriate insertion and it's because she just
8 rambles on without any control from the lawyer.

9 MR. SLATER: I'm sorry.

10 THE COURT: Please. I don't know
11 how long you're going to keep her on and I don't
12 know how much of tomorrow you're going to use on
13 her. You say we've got two other doctors. We've
14 got to get his doctor on sometime. Is it
15 tomorrow?

16 MR. HYDE: Wednesday.

17 THE COURT: Wednesday. Okay.
18 We've got all day tomorrow, then, to do whatever,
19 I guess.

20 MR. BALL: But my objection is
21 that she should not be talking about the lungs.
22 That was your ruling. And I think it was
23 inadvertent but I'd just ask you to tell her not
24 to talk about the lungs anymore.

25 MR. SLATER: I'll be happy to do

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1 that.

2 MR. BALL: Thank you.

3 MR. SLATER: But I will say, Your
4 Honor, it's all over the medical records. It's a
5 diagnosis of what she was dealing with.

6 THE COURT: Well, that's for
7 somebody else to deal with. It wasn't her. Just
8 stay out of it.

9 MR. BALL: Just tell her to not do
10 that anymore.

11 THE COURT: We're going to quit
12 here about 5:00, so you've got about 22 minutes.

13 MR. SLATER: I think she'll be
14 done before that. I've been narrowed so much, I
15 probably won't have much more to do.

16 THE COURT: Okay.

17 MR. SLATER: I feel bad for the
18 family, but I'll do what I got to do.

19 THE COURT: All right.

20 (The proceedings returned to open
21 court.)

22 MR. BALL: I'm just going to walk
23 over and speak to Dr. Weber for a moment.

24 THE WITNESS: Yeah. I wish you
25 would.

1 (There was a discussion off the record.)

2 Q. (By Mr. Slater) The various conditions
3 that you've talked about, it's your opinion that
4 they were set in motion by the infection of the
5 mesh and that that carried forward to these
6 conditions that you testified to?

7 A. Yes.

8 MR. BALL: Object to the form and
9 foundation.

10 THE COURT: Oh, I'll overrule that
11 this time, but please, please couch it in
12 questions, okay?

13 Q. (By Mr. Slater) Doctor, there's
14 reference in these records here in this
15 hospitalization in June of '09 to a 30-pound
16 weight loss and debilitation.

17 What does that mean, "debilitation," and
18 why was this weight loss occurring?

19 A. Yes.

20 So the debilitation, the fact that she
21 was bed-bound.

22 So, you know that colloquial phrase "use
23 it or lose it." If you don't use your muscles,
24 they very quickly lose their mass. They lose
25 muscle mass. She's not taking in nutrition, and

1 so -- enough nutrition, so one of the ways the
2 body tries to compensate for that is actually to
3 start breaking down the muscles because that is a
4 source of protein.

5 So that's why she ended up with the
6 G-tube was to try to supplement her nutrition and
7 to try to improve her chances of -- of being able
8 to come back, which unfortunately was not
9 successful.

10 **Q. It says that she is very debilitated and**
11 **ambulates short distances in the home but mainly**
12 **gets around in a wheelchair.**

13 **In comparing that to her condition before**
14 **all this started, can you tell the jury about that**
15 **and whether that's significant to you?**

16 A. Yes. She -- before the surgery, before
17 the Prolift, she was a very active woman. She
18 exercised at home. She exercised at a community
19 gym. She attended water aerobics classes. She
20 was active in her community.

21 So that was a completely drastic change
22 from -- from someone at that level of activity to
23 someone who has essentially been bed-bound or
24 wheelchair-bound with very short stretches of
25 getting up on her feet.

1 Q. And there's a note in here that
2 "Dr. Adkins is planning" -- and this was in June
3 of 2009. June 26. "Dr. Adkins is planning to do
4 a cystectomy for removal of her bladder after the
5 patient is medically stable and stronger. The
6 surgery is scheduled for July 14."

7 What are they talking about there?

8 A. So because of the extent of her
9 vesicovaginal fistula, it was so large and there
10 was so much tissue damage in the -- in the front
11 wall of the vagina and the bladder, the doctor
12 didn't even think it was feasible to attempt a
13 repair to try to recreate that separation between
14 the vagina and the bladder.

15 So his solution was to remove the bladder
16 altogether, which is called a cystectomy, and then
17 do a urinary diversion, kind of like a colostomy,
18 except for the urinary part, where the urine would
19 actually come out to the surface and be collected
20 in a bag and then get emptied and -- and all that
21 stuff.

22 And that surgery was scheduled and
23 rescheduled, but Mrs. Budke never came to the
24 point where she was strong enough to undergo that
25 kind of really extensive surgery.

1 Q. So she was told she needed to have her
2 bladder removed from her body and that was how she
3 was going to live going forward, but she never was
4 strong enough to do it?

5 A. That's correct.

6 Q. I'd like to put up Exhibit P2106 now, the
7 scout film from August 2, 2009.

8 MS. JONES: I'm sorry, Counsel. I
9 didn't understand what you said it was.

10 MR. SLATER: It's a scout film
11 from a CAT scan of August 2, 2009.

12 Q. (By Mr. Slater) So Dr. Weber, what are
13 we looking at here?

14 A. So this again is a scout film. So this
15 is a picture taken preliminary to a CAT scan, just
16 kind of an overview of Mrs. Budke's body, and I
17 just want to orient you here briefly.

18 So again, she's lying on her back in the
19 CAT scan machine. You can see obviously this
20 (indicating) is towards her head. This
21 (indicating) is towards her feet. The rib cage.
22 This white area (indicating) is opaque material in
23 her stomach. This (indicating) is her stomach.
24 So it's just filled with fluid that turns white
25 when it's under an x-ray, okay?

1 Her spine, her pelvic bones, her hips
2 (indicating). Okay?

3 Q. What I'd like to do now is I'd like to
4 put a side by side of 2106 and 2107, please.

5 Dr. Weber, these are the scout films. On
6 the left is January 22, 2009. On the right is
7 August 2, 2009.

8 Can you tell the jury what's significant
9 about that, please?

10 A. So you remember we saw this picture
11 earlier of the CAT scan that Mrs. Budke had when
12 she first became acutely ill, and you can see the
13 same bony structures, right? The spinal column,
14 the hip bones.

15 And what you see here on the outside --
16 the outline of the body are some -- you know, the
17 normal skin folds and a little bit of fat
18 underneath the skin. Pleasingly plump.

19 Now we see, right before Mrs. Budke died,
20 she has no fat anymore. All of that has been
21 burned up in her body's fight to stay alive, and
22 she lost that fight.

23 Q. Do you have an opinion as to what --
24 whether what we're looking at right there in this
25 process you just described is related to the mesh

1 erosion and the process that began with that?

2 A. Yes, I do.

3 Q. And what's that opinion?

4 MR. BALL: Object to the form and
5 the foundation and the qualifications for that.

6 THE COURT: Can you lay a little
7 better foundation?

8 Q. (By Mr. Slater) Doctor, based on your
9 knowledge, skill, and experience, are you able to,
10 from looking at all the medical records, follow
11 the different conditions that Joan suffered from,
12 and is that within your field of expertise to
13 understand how that has impacted -- how that
14 impacted on her physical well-being?

15 A. Yes.

16 Q. And explain why.

17 Explain what about your training and
18 experience allows you to talk about that.

19 A. Well, in my field of urogynecology, this
20 does predominantly affect older women, so I have a
21 large range of experience caring for older women,
22 bringing them through the surgical process,
23 managing complications that arise, going through
24 the steps like we talked about before, the
25 differential diagnosis and calling in consultants,

1 when needed, to manage these things.

2 I've -- that's the standard medical
3 practice that I had for more than 15 years.

4 **Q. The medical conditions that Joan had in**
5 **this process, are these things that you treated in**
6 **your own medical practice?**

7 A. Yes.

8 MR. SLATER: Okay, Your Honor?
9 Thank you.

10 **Q. (By Mr. Slater) Do you have an opinion,**
11 **to a reasonable degree of medical certainty, as to**
12 **whether the process that you've described that**
13 **began with the mesh erosion and the infection of**
14 **the mesh is related to what we're seeing here and**
15 **this process that you've talked to the jury about**
16 **and that is documented in the medical records and**
17 **you've talked about?**

18 A. Yes, I have an opinion.

19 **Q. And what is your opinion?**

20 A. My opinion is that this entire cascade of
21 events that resulted in Mrs. Budke's death was
22 initiated by the Prolift mesh implantation.

23 **Q. And does that mean in your opinion that**
24 **there's a causal connection and a causal link?**

25 A. Yes.

1 **Q. And do you hold that opinion to a**
2 **reasonable degree of medical certainty?**

3 MR. BALL: Object to the form and
4 the foundation, Your Honor.

5 THE COURT: Well, I'll let her
6 answer it. I've gone this far.

7 MR. SLATER: Thank you.

8 **Q. (By Mr. Slater) And you hold that**
9 **opinion to a reasonable degree of medical**
10 **certainty?**

11 A. Yes, I do.

12 MR. SLATER: Your Honor, I think
13 we've reached the point where we can stop our
14 direct testimony of Dr. Weber. I understand your
15 rulings on the other issues so I think we're done
16 for today.

17 THE COURT: All right. Ladies and
18 gentlemen, that --

19 Anything else? Do we have something --
20 did you --

21 MS. JONES: No. I was ready to
22 begin cross-examination.

23 THE COURT: Well, I was going to
24 say, do you want -- you've got 12 minutes. Do you
25 want to use some of that?

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1 MS. JONES: It's totally up to
2 Your Honor.

3 THE COURT: Oh, no, it's fine with
4 me. It's fine with me. I just want to let them
5 out of here when it's let-out time, so, you know,
6 if you've got something -- a couple, three
7 questions you'd like to ask, well, let's do it.

8 MS. JONES: Frankly, I'll leave it
9 up to the jury, Your Honor. I'm happy to go ahead
10 and start or --

11 THE COURT: Well, yeah. I don't
12 know that you can finish because my guess is you
13 can't cross-examine her in 12 minutes.

14 MS. JONES: No, no, no, I can't
15 finish.

16 THE COURT: No way, Jose. And I'm
17 not going to keep them here till 6:00, so, you
18 know, if you've got two or three questions you
19 want to ask, and then we'll get rip-roaring in the
20 morning, that's fine.

21 MS. JONES: All right. Let me
22 just ask a couple of questions.

23 THE COURT: All right. Sure.

24

25

1 CROSS-EXAMINATION

2 QUESTIONS BY MS. JONES:

3 Q. Dr. Weber, Judge Hass told the jury this
4 morning and I think it's true. You never
5 implanted a Prolift, did you?

6 A. No. That's right.

7 Q. And you never treated a woman that had a
8 Prolift, did you?

9 A. No, I don't believe so.

10 Q. You never examined a woman that had a
11 Prolift, did you?

12 A. No, I don't think so.

13 Q. You never treated a woman like Mrs. Budke
14 that had a Prolift, did you?

15 A. No. No, I didn't.

16 Q. You never -- you never examined a woman
17 with what you claim to be mesh contracture, did
18 you?

19 A. No. That's right. I'm relying on the
20 medical records in that case.

21 Q. And those medical records in this
22 particular case don't mention the word
23 "contracture" anyplace, do they?

24 A. No, not in so many words.

25 Q. That word does not appear anywhere in

1 **Mrs. Budke's medical records, does it?**

2 A. No, I don't believe it does.

3 Q. Now, it's also true that before you
4 became involved, you never went to any
5 professional education sponsored by Ethicon?

6 A. No, I did not.

7 Q. You never -- I'm sorry, I lost my train
8 of thought. Just bear with me.

9 You never went to any professional
10 education sponsored by Ethicon with respect to
11 Prolift, did you?

12 A. No, I did not.

13 Q. And before you were hired by Mr. Slater,
14 you never looked at any of the product materials
15 on Prolift, did you?

16 A. No, that's not true.

17 Q. I think you told us -- and if not, we can
18 come back and talk tomorrow.

19 I thought you told us that you'd never
20 seen the instructions for use on Prolift before
21 then.

22 A. Oh, I thought you said the product
23 labeling. I was being more inclusive than that.

24 Q. I said product literature.

25 You've never seen -- you never saw the

1 instructions for use on Prolift before you started
2 working for Mr. Slater, did you?

3 A. Okay. I -- I was interpreting your use
4 of the word more broadly.

5 So you're correct. I had not seen the
6 IFU.

7 Q. Never had seen the patient brochure, had
8 you?

9 A. No, I don't think so.

10 Q. Never gone through and reviewed internal
11 company documents of any medical device
12 manufacturer, had you?

13 A. No. Those are not available to the
14 public.

15 Q. And it's fair to say, Dr. Weber, that
16 you've done -- have not participated in any of the
17 clinical trials that relate to Prolift, have you?

18 A. That's correct.

19 Q. You never participated in any of the
20 clinical trials that were done by the TVM group,
21 did you?

22 A. That is correct.

23 Q. And the transvaginal mesh group was a
24 group of doctors in Europe?

25 A. In France, yes, uh-huh.

1 Q. And you know there were also doctors in
2 the United States that were working with Ethicon
3 to develop the tools to work with the mesh that
4 became the kit?

5 A. Yes.

6 Q. And you know that the studies done by the
7 transvaginal mesh group were published in the
8 medical literature for all of the doctors to see,
9 correct?

10 A. Eventually, uh-huh.

11 Q. And I think you told us -- and correct me
12 if I'm wrong -- that you were not aware of any
13 medical device mesh kit, transvaginal mesh
14 product -- let me start over. I got a little
15 confused there.

16 I think you've agreed with us that there
17 was not a single transvaginal mesh product to
18 treat prolapse for which there were more clinical
19 studies published in the medical literature than
20 Prolift. Correct?

21 A. After its launch, correct.

22 Q. Well, without regard to its launch or
23 when it's out there, there are more medical
24 studies done to evaluate the safety and efficacy
25 of Prolift than relate to any other medical device

1 used -- transvaginal mesh medical device used to
2 treat prolapse, correct?

3 A. Yes.

4 Q. And the same is true of Gynemesh PS?
5 That there's no other product other than Prolift
6 on which there have been more medical studies
7 published in the medical literature?

8 A. I don't know that for a fact, but I don't
9 have any reason to dispute that.

10 Q. If you told us in your deposition that
11 you agreed with that and that you did not know of
12 any product in which there had been more medical
13 studies done other than Prolift --

14 Let's go back and see if I can get my --

15 If you told us in your deposition that
16 other than Prolift, Gynemesh PS was the most
17 studied -- in terms of published medical
18 studies -- transvaginal mesh products on the
19 market, you would agree with that, wouldn't you?

20 A. And you're restricting this to prolapse?

21 Q. I'm talking about products to treat
22 pelvic organ prolapse.

23 A. Prolapse, yes. Yeah.

24 Q. Which is what we're here about today,
25 correct?

1 A. Yes.

2 Again, I don't have any reason to dispute
3 that.

4 Q. And in fact, you do know that there were
5 other transvaginal mesh products produced by
6 competitors of Ethicon on the market used for
7 exactly the same product -- purpose, correct?

8 A. Yes.

9 Q. And what you're telling this jury today
10 is that compared to any of those other products,
11 Prolift was the best studied in terms of the
12 published medical literature?

13 A. Yes.

14 MS. JONES: Your Honor, I think
15 it's five till and I don't want to get in trouble
16 with the jury and I'll just stop there.

17 THE COURT: All right. That's a
18 good time to stop. We'll start in the morning at
19 9:00 promptly, and if you want me to, I'll
20 re-swear her or however you want to do it. Just
21 let me know.

22 Okay. Ladies and gentlemen, I'm going to
23 get you out of here at 5:00.

24 Justice requires that you not make up
25 your mind about the case till all the evidence has

1 been seen and heard. You must not discuss this
2 case among yourselves or with anyone else or
3 comment on anything you've heard or learned in
4 this trial until the case is concluded and you
5 retire to the jury room for your deliberations.

6 Also, you must not remain in the presence
7 of anyone who is discussing the case when the
8 court is not in session.

9 And having said that, then I will excuse
10 you. I will see you in the morning. If you'll be
11 here, hopefully we'll line you up at 9:00 and
12 within a reasonable few minutes get you in here.

13 If you got anything in there or anything,
14 let us know or -- that you need tonight, because
15 I'm not -- I haven't tried to be tough with
16 everybody about this leaving the courtroom -- the
17 jury's no problem, but, you know, these folks work
18 all day, and 5:00 is their quitting time, and I
19 just don't want to fight with the county
20 commission about keeping them here a long time, so
21 we'll get everything together and we'll get out of
22 here as quick as we can. Although if we've got
23 anything to discuss, stick around and we'll talk
24 about it.

25 (The following proceedings were

1 held in the courtroom outside the presence of the
2 jury:)

3 THE BAILIFF: They're gone.

4 THE COURT: The jury's out.

5 Anything we need to talk about before we go home?

6 MR. BALL: Yeah. I'd just like to
7 confirm what's going to happen tomorrow.

8 THE COURT: Okay.

9 MR. BALL: So we're going to
10 obviously finish Dr. Weber. What else will happen
11 tomorrow?

12 MR. SLATER: Well, it depends when
13 you finish. I believe it's a little bit depending
14 on that.

15 MR. BALL: We'll finish in the
16 morning for sure.

17 MR. SLATER: Well, we'd like to be
18 able to play our videos, which I think we're still
19 waiting for answers on a lot of videos. We were
20 waiting up late last night and never got some
21 answers, so we're trying to work out those issues.

22 THE COURT: Oh, okay. Well, yeah,
23 that's fine.

24 MR. SLATER: And that's holding us
25 up.

1 THE COURT: Let me know the
2 compromise.

3 MR. BALL: What about any live
4 witnesses tomorrow besides Dr. Weber?

5 MR. SLATER: Well, you know,
6 honestly we would like to call perhaps some of the
7 family members and we talked, we'd like to call
8 Dr. Godleski and use the time as well as we can.

9 And then we have Dr. Dixon and Dr. Neal's
10 videos. I think they're pretty much done. So we
11 have plenty to do.

12 MR. BALL: Your Honor, as I stated
13 this morning, I think I'm entitled to finish
14 Dr. Simpson --

15 THE COURT: Well, that's getting
16 to be the sticking point there.

17 MR. BALL: Yeah. If he wants to
18 put on video -- if he wants to do Dr. Weber and
19 then videos the rest of the day to fill it up, or
20 if he wants to put --

21 I just need to know whether Dr. Godleski
22 is coming tomorrow so I can prepare. I just need
23 to know that.

24 MR. SLATER: He may. He's going
25 to be here and if he's ready to go to the witness

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1 stand, he will. Otherwise, he'll go Wednesday.

2 MR. BALL: You know, I think I'm
3 entitled to know here at 5:00 who is coming the
4 next day and who isn't.

5 THE COURT: Well, do you have him
6 scheduled for tomorrow?

7 MR. BERGMANIS: How long are you
8 going to cross tomorrow?

9 MR. SLATER: He's coming in late
10 tonight. I don't know when he's getting in,
11 Judge.

12 (Court reporter interruption.)

13 THE COURT: Let's go off the
14 record.

15 (Proceedings recessed for the day at 4:59 p.m.)

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1 REPORTER'S CERTIFICATE

2 I, CHARLES W. MOTTER, Certified Court
3 Reporter, certify that on January 12, 2015, I was
4 the acting official court reporter for the Camden
5 County Circuit Court at Camdenton, Missouri; that
6 I was present and reported all of the proceedings
7 in Donald Budke, Plaintiff, vs. Lake Area Women's
8 Center of Obstetrics & Gynecology, a subsidiary of
9 Lake Regional Medical Management, Inc., f/k/a Lake
10 of the Ozarks Medical Management, Inc.; Becky
11 Simpson, M.D.; Johnson & Johnson, a New Jersey
12 Corporation; Ethicon, Inc., a New Jersey
13 Corporation; and Gynecare Worldwide, a division of
14 Ethicon, Inc., a foreign corporation, Defendants,
15 Case No. 10CM-CC00085. I further certify that the
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Acting Official Court Reporter

22 Camden County Circuit Court at Camdenton, Missouri

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1 IN THE CIRCUIT COURT
2 TWENTY-SIXTH JUDICIAL CIRCUIT
3 CAMDEN COUNTY, MISSOURI
4 DONALD BUDKE,)
5)
6 Plaintiff,)
7)
8 v.) No. 10CM-CC00085
9)
10 LAKE AREA WOMEN'S CENTER OF)
11 OBSTETRICS & GYNECOLOGY,)
12 a subsidiary of Lake)
13 Regional Medical Management)
14 Inc., f/k/a Lake of the)
15 Ozarks Medical Management,)
16 Inc.; BECKY SIMPSON, M.D.;)
17 JOHNSON & JOHNSON, a)
18 New Jersey corporation;)
19 ETHICON, INC., a New Jersey)
20 corporation; and)
21 GYNECARE WORLDWIDE,)
22 a division of Ethicon, Inc.)
23 a foreign corporation,)
24)
25 Defendants.)

14 TRANSCRIPT - JURY TRIAL
15 VOLUME VII
16 January 13, 2015

19 On January 13, 2015, the above cause came on
20 for Jury Trial before the HONORABLE WILLIAM R.
21 HASS, Judge of the Camden County Circuit Court at
22 Camdenton, Missouri, a jury of 12 and three
23 alternate jurors.

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1 (Proceedings began at 8:58 a.m.)

2 (The following proceedings were
3 held in the courtroom outside the presence of the
4 jury:)

5 THE COURT: Okay.

6 MR. HYDE: Can I tell you what the
7 issue is, Judge?

8 THE COURT: Yeah. Let's get
9 everybody here where they can hear you.

10 MR. HYDE: We thought best address
11 it before the cross-examination of Dr. Weber.

12 It was brought up her charges and fees
13 yesterday, which is appropriate. The fact is,
14 she's been paid almost a million dollars by
15 plaintiff's firm. Okay? And so we intend to ask
16 her about that, but don't want to violate the
17 ruling and the motions in limine on all these
18 other cases that are filed and pending, which, of
19 course, would not be relevant.

20 So my view on this is very simple.

21 The law is very clear that other lawsuits
22 would not be relevant and highly prejudicial in
23 this case, and she will not be asked about those,
24 but certainly the witness connection to the
25 plaintiff's lawyer is very relevant.

1 And of course that instruction has
2 already been given to the jury in -- in
3 Instruction 201 --

4 THE COURT: In Instruction 201.

5 MR. HYDE: -- where the interest
6 of the witness in the outcome of the case, the
7 behavior, the relationship of the witness to any
8 of the parties, et cetera, is to be considered by
9 the finder of the fact. In this case, the jury.

10 So it's simply our view that's obviously
11 relevant. We intend to do it. I just thought if
12 there's going to be some kind of problem with it,
13 we'd just bring it up ahead of time.

14 MR. BALL: We agree with that same
15 position. I'd just add in that since January of
16 2010, Ms. Weber -- Dr. Weber has testified that
17 her full-time -- that her only employment, her
18 only employment, is working for Mr. Slater.

19 So -- I'm not sure whether it's since
20 January 2010, but certainly presently and for the
21 past few years, that has been her employment.

22 And the plaintiff injected into the case
23 that she'd done a 500-page report, that she's
24 reviewed thousands of pages of testimony, that
25 she's reviewed hundreds of thousands of pages of

1 documents, and he's created an impression that
2 that was all done for \$88,000 and that's just not
3 accurate.

4 And so for all of the reasons that Kent
5 said plus what we say, we just want to know that
6 we're going to ask those questions and we are not
7 thereby opening the door to anything else.

8 MR. SLATER: Good morning, Judge.

9 THE COURT: Good morning, sir.

10 MR. SLATER: How are you?

11 THE COURT: I'm fine.

12 MR. SLATER: Good, thanks.

13 We never said that she was paid \$88,000
14 to look at all those documents. We said, "How
15 much time have you spent in this case," and she
16 said how many hours she spent in this case, and
17 that was a truthful statement.

18 Nobody in the world would pay Dr. Weber
19 the amount of money and have the amount of time
20 spent for one case for this case.

21 Dr. Weber --

22 THE COURT: I didn't understand
23 that.

24 MR. SLATER: And I just want to
25 let you know the full background and then

1 Mr. Anderson is also going to give you some
2 background because Judge Goodwin has ruled --
3 because all the experts that come in front of him
4 are not just acting as an expert in one case but
5 they're doing what Dr. Weber does.

6 THE COURT: Sure. I mean, I
7 understand that.

8 MR. SLATER: And here's the fact.
9 Dr. Weber is working as an expert available to
10 testify in 7,000 cases in New Jersey, okay?

11 We have 7,000 cases in New Jersey, and I
12 retained her to not just be the expert in one case
13 or two cases but to be available -- whenever a
14 case comes to trial in that litigation to be
15 available to be able to testify in those cases.

16 That's what she's retained to do and now
17 here she is in Missouri and she was ready to
18 testify in Joplin earlier this year.

19 She's also working as the expert -- she's
20 already testified in Linda Gross' case, which is a
21 two-month trial in New Jersey. She's ready to
22 testify in the Wicker case, which we're hoping is
23 going to be scheduled in two months in New Jersey.
24 We have several other cases that we're pushing
25 hopefully towards trial. She is available to work

1 in those cases.

2 The work she's done is not limited to
3 this case and she hasn't been paid just in this
4 case on the other things.

5 I didn't mislead the jury. We asked the
6 time she spent just on the Budke case, looking at
7 these records, these depositions, doing what she's
8 done here. She told the truth.

9 If they want to ask her the total amount
10 she's been paid, we don't want to mislead the jury
11 about anything. We want them to know the absolute
12 whole truth. And the whole truth is that time has
13 been spent in a lot of women's cases. She's
14 looked at the records I think of about 15 other
15 women. I'm talking in-depth, because we have
16 other cases that are going through the bellwether
17 discovery process in New Jersey and then it gets
18 whittled down.

19 She's constantly looking at cases for me
20 because I represent 300 women. And lawyers from
21 around the country call me and say, "Hey, I have a
22 question about this, I have a question about
23 that," and I consult with her, because as lead
24 counsel of the New Jersey litigation, I have an
25 obligation to be available to lawyers around the

1 country to consult and help them and share my
2 knowledge.

3 So if they want to ask about the total
4 amount, I'm happy for them to do that, but she has
5 to be allowed to tell the truth to the jury --

6 THE COURT: Well, right.

7 MR. SLATER: -- about what she's
8 done, and that way the jury won't be misled at
9 all.

10 And as Mr. Anderson can tell you, Judge
11 Goodwin has ruled he doesn't even want them to
12 know the total amount an expert has been paid. He
13 says, "Tell them the amount they've been paid on
14 that matter alone," because he doesn't want to get
15 into all this, and he's ruled that way, is my
16 understanding. Mr. Anderson has tried cases in
17 front of Judge Goodwin.

18 MR. ANDERSON: Your Honor, if I
19 could real quick.

20 THE COURT: Sure.

21 MR. ANDERSON: Unlike a lot of the
22 cases that Your Honor may see, this is one piece
23 of a larger puzzle, and --

24 THE COURT: Yeah. It's a small
25 piece of the pie.

1 MR. ANDERSON: Well, it's just --

2 THE COURT: Well, I mean, yeah,
3 it's --

4 MR. ANDERSON: There's a lot of
5 cases involved --

6 THE COURT: Yes.

7 MR. ANDERSON: -- and so in the
8 MDL context, we have generic experts and we have
9 case-specific experts, and the general liability
10 experts are brought in to testify for all of the
11 women in the particular MDL.

12 THE COURT: Gotcha.

13 MR. ANDERSON: Yes, sir.

14 And so what Judge Goodwin has recognized
15 is in his courtroom, he says, "You know, it's not
16 going to be fair to talk about all of the cases.
17 You can ask them about the case that's involved
18 and you can ask them how much money they've made
19 in that case."

20 And in fact, it's interesting that the
21 defendants are on the other side of this argument
22 before Your Honor this morning, because not a
23 month ago we were sitting in Judge Goodwin's
24 chambers and Ms. Jones said, "Your Honor, I want
25 to make sure that it's clear that when we question

1 our experts about how much they've been paid,
2 we're only going to talk about this case, in line
3 with your prior rulings, Judge. I want to make
4 sure of that."

5 And he said, "Yes, Ms. Jones, that's what
6 we're going to do."

7 Now we find ourselves, when it's
8 convenient, they -- they're on the other side of
9 the issue saying, "Oh, no, we want the expert --
10 we want to be able to ask questions about all the
11 money they've made."

12 And so it makes sense in the context of a
13 case where there's a limited number of experts who
14 have to look at tens of thousands of cases, or be
15 responsible for them as a general expert, that the
16 jury hear what they did, the work that they did in
17 this case.

18 Otherwise, if they -- you know, let's do
19 what's fair. Let's make sure the playing field is
20 level here. If they want to get into that, then
21 we got to talk about all the other women in the
22 other lawsuits that she's working on.

23 MS. JONES: Could I just clear up
24 one thing?

25 THE COURT: Sure.

1 MS. JONES: Just so we're clear,
2 the colloquy that Mr. Anderson reported did, in
3 fact, happen. It happened as a result of an event
4 in another trial where there had been a
5 stipulation and an agreement that we were only
6 going to address payments in that particular file
7 and that agreement was not abided by, and so that
8 was -- it was a matter of trying to confirm that
9 agreement at that point.

10 All I would say in this case is, it is
11 our position that the bias and -- the amount that
12 the plaintiff has been -- excuse me, that the
13 witness has been paid demonstrates her bias,
14 without regard to the amount of work that she's
15 done, and as Mr. Hyde has suggested, the other
16 cases are totally irrelevant.

17 The reason we're having this discussion
18 is, we don't want to get into a situation where
19 there's discussion of all of the other cases. In
20 fact, when there was a mention of other cases
21 yesterday, we were a little bit concerned but let
22 it go.

23 I will say that Dr. Weber has testified
24 that she's only consulted in six cases. Now, that
25 was six months ago when she'd only been paid

1 eighty- -- \$800,000, but --

2 MR. BALL: So, Your Honor, we have
3 two principles of law here.

4 We have one principle is you shouldn't be
5 talking about other cases in front of the jury --

6 THE COURT: I don't want to do
7 that.

8 MR. BALL: -- and we have another
9 principle that says, according to the -- wherever
10 the book goes -- according to the MAI and
11 long-established law that you're entitled to
12 question about the financial interest of a witness
13 for possible bias.

14 Just because -- so that is an established
15 principle. The other is an established principle.

16 The plaintiffs are trying to say if we
17 exercise our right on one established principle,
18 that that overrules the other established
19 principle, and that's not the case. That's not
20 the case.

21 What they're trying to do is to prevent
22 us from showing the financial interest of this
23 witness by holding this threat of other lawsuits
24 which are clearly not admissible, and they're
25 trying to tie the two together and that should not

1 be allowed. They're two different issues. One is
2 financial interest; the other is other lawsuits.

3 MR. ANDERSON: Another principle
4 that applies here, Your Honor, whether it's
5 Missouri or Alaska, and that's fundamental
6 fairness and making sure that each party is able
7 to put in something that is balanced. And you've
8 just heard it. Judge Goodwin has ruled the other
9 way. No one disputed that. And now you've heard
10 from counsel, "Your Honor, we want it both ways.
11 We want to be able to put in the money but we
12 don't want them to talk about the cases." That's
13 an unlevel playing field --

14 THE COURT: Well, I think --

15 MR. ANDERSON: -- and that's not
16 fair.

17 THE COURT: I think night follows
18 day. I think if you talk about one, you got to
19 talk about both, to some extent.

20 MR. ANDERSON: Yes.

21 THE COURT: Here's the whole
22 thing. I made a quip and I think it's on the
23 record. And bless my heart, I'm going to be real
24 truthful with you. I probably paid more attention
25 to Kent way back early on. I said, "How do you

1 work these documents?" Because I began to see
2 that everybody was carrying boxes and boxes and
3 boxes. And he told me something and I don't think
4 that's any secret or has anything particularly to
5 do with this case. He said, "We're at the point
6 in this type of litigation where you don't
7 exchange paper, you exchange hard drives."

8 MR. SLATER: They give us hard
9 drives usually with a hundred to 200,000 documents
10 -- pages of documents at a time.

11 THE COURT: This is kind of -- I
12 mean, and as far as they went but that's what I
13 kind of gathered. Then I --

14 MR. SLATER: And then they put
15 them on computer systems and people search them
16 with -- I don't understand how to do it.

17 THE COURT: Right. And I know
18 it's out there -- a lot of is out there in the
19 cloud somewhere.

20 So I made the comment, just kidding -- I
21 think it was while some of y'all were around; it
22 was up here after a pretrial -- I said, "Well, how
23 long am I supposed to take to read this?" And he
24 made some comment like at that time maybe there
25 were -- I don't remember, what, 10 million page --

1 or maybe 2 million -- 2 million pages, and now you
2 say it's more like 10.

3 And I said, "Well, that would take
4 while."

5 He said, "I -- just calculating it out,
6 if you sat and read 8 hours a day 5 days a week,
7 you'd probably get it done in about 13 years."

8 And that's kind of -- I made that quip on
9 the record, "I don't think I'm going to spend -- I
10 don't think I have 13 years I can spend on reading
11 all this record." I made that comment. You
12 know --

13 MR. SLATER: You said that in
14 front of the jury yesterday or the day before --

15 THE COURT: Yeah.

16 MR. SLATER: -- and I think you
17 got a good laugh about it.

18 THE COURT: Yeah, and everybody
19 kind of laughed about it.

20 But here's the whole thing. I understand
21 where both of you are coming from, and I think
22 that if they want to raise the issue that she's
23 made more than that amount of money, then she's
24 got a right to say, "Well, yeah, but I -- this is
25 not the only case I've got."

1 I mean, nobody -- surely nobody that
2 hears this testimony is going to think that she
3 read all that -- that much stuff for that amount
4 of money. I don't know. Because -- well, we know
5 that it didn't take 13 1/2 years, and I doubt, if
6 she got on the stand under oath, she'd say "I've
7 read all 10 million pages."

8 MR. SLATER: And I doubt I'd be a
9 very good businessman as a lawyer if I hired her
10 and --

11 THE COURT: Yeah.

12 MR. SLATER: -- paid that much in
13 just one case.

14 THE COURT: I was going to say, if
15 you're paying that kind of money, could I just
16 maybe retire and do -- carry your books around or
17 something? I mean, you know, if people got that
18 kind of money to give away.

19 I don't want to mishandle this, and I've
20 tried to watch what these other judges are doing
21 to the extent that I could, because they've had a
22 lot more experience at it than I have.

23 Somebody made comment a minute ago and I
24 don't know that much about all of this. I know
25 that I've got this case here and it's -- I'm

1 about -- well into it. Not quite halfway, but I'm
2 well into the swamp. And somebody mentioned a
3 case in Joplin. Now, I don't know anything about
4 that. Don't care anything about it. But as far
5 as I know, that's about all of this litigation
6 that's going on in the Show-Me state right now.
7 There may be more.

8 MR. SLATER: We had three cases in
9 Joplin. They settled.

10 THE COURT: Okay.

11 MR. SLATER: They were actually
12 the only three cases that have settled in the
13 United States with J&J.

14 THE COURT: Okay. Well, see, I
15 didn't even know that, so it's not like I've
16 snooped around.

17 MR. SLATER: No, no.

18 THE COURT: All I'm saying is I
19 don't have much jungle drum around here from my
20 other judge friends or lawyers who say, "Hey, we
21 know a lot about that," because, you know, when
22 I -- when I had mentioned that I had this
23 Ethicon/Johnson & Johnson case, they said, "I
24 didn't know there was any of that going on around
25 here," and I said, "Well, come to Camdenton."

1 How, then, do you suggest -- I don't want
2 to build an error in or something here, but how do
3 you suggest we do this? Because I think -- I
4 think the jury would have a question, maybe, in
5 their mind, has she spent all this many hours on
6 this case that we're hearing.

7 MR. SLATER: Our suggestion is
8 it's up to them if they want to open the door on
9 this, and, you know, the law being where -- and
10 I'm just reading from, you know, boilerplate law
11 from State v. Shockley. It's a Missouri Supreme
12 Court case --

13 THE COURT: All right.

14 MR. SLATER: -- where the Court
15 says, "Where the defendant has injected an issue
16 into the case, the plaintiff may be allowed to
17 admit otherwise inadmissible evidence in order to
18 explain or counteract a negative inference raised
19 by the issue. Defendant objects." Basically
20 open-the-door stuff.

21 So that law is -- you know, that's the
22 black letter law in any state in the country.

23 It's up to them. I just say if they
24 raise the issue, as Mr. Anderson says, let's tell
25 the jury the truth and not mislead the jury. So

1 we didn't inject the issue in. If they want to
2 raise it, she should be allowed to tell the jury
3 the truth.

4 THE COURT: Let me ask you this --
5 no. Go ahead. Go ahead.

6 MR. BALL: Could I?

7 THE COURT: I'm sorry.

8 MR. BALL: If I could respond to
9 that, Your Honor, before we get too far.

10 THE COURT: Yes.

11 MR. BALL: They injected this
12 issue by create- -- by saying she did this 5-0-0
13 page report --

14 THE COURT: Yes.

15 MR. BALL: -- and she read all of
16 the testimony and all of the documents and things.
17 They're -- they didn't say, "You did \$88,000 to
18 read Mrs. Budke's records" and that type of thing.

19 MR. SLATER: But we did.

20 MR. BALL: Excuse me.

21 They went into considerable detail as to
22 what all she had done. They had a list up there,
23 "Materials Reviewed." It had like 10 bullet
24 points on it, okay?

25 So they've created -- they have created

1 that impression. They're the ones that have
2 injected the issue. And it seems to us that
3 having done that, having put in that she did a
4 500-page report and having put in how much time
5 she read and she read every one of things, that
6 we're entitled to show her -- the amount of money
7 that she has charged here.

8 Now, if they -- so the -- and then the
9 flip side of that -- this is all a weighing
10 process.

11 The flip side of that, of them turning
12 around and saying, you know, "She's worked --
13 there's thousands of cases pending," that's just
14 unfairly prejudicial and improper.

15 If they want to say something like "You
16 have also worked on some other cases," period --
17 period -- then that's something that could be
18 considered. But to get into details beyond that
19 is inappropriate.

20 MR. OVERBY: Your Honor, if I
21 could, just very briefly.

22 THE COURT: Go ahead.

23 MR. OVERBY: What I would do in
24 this case is what we do in every case.

25 If, for example, there's an expert

1 witness who testifies frequently for a particular
2 law firm, you might ask them "How much money have
3 you been paid by X?" By that law firm.

4 That's not getting into -- because I
5 think there's a difference if you say "You've
6 looked at all this stuff and you got paid X
7 dollars to look at all that stuff." That clearly
8 could, potentially at least, open up the fact that
9 she's looking at all that stuff for multiple
10 cases.

11 The question, "How much money have you
12 been paid by Mr. Slater or his firm," though, goes
13 straight to her credibility. It's no different
14 than any other case that we have when an expert
15 gets paid a hundred thousand dollars a year. We
16 all know that's not on one case. Or has been paid
17 X dollars from a firm. Of course it's on other
18 cases.

19 It's not really opening up the details of
20 what she did, but it goes straight to her
21 credibility and her incentive to testify the way
22 that she does, which is part of what the jury
23 is --

24 THE COURT: Well, that's -- it's
25 true that the first instruction I gave in this

1 case and every other civil case states that the
2 jury can consider the weight to give to the
3 testimony based on different things, and one
4 incentive is "What have you been paid to do it."

5 MR. BALL: Right.

6 THE COURT: I don't -- here's the
7 whole thing. I don't want to open a can of worms
8 because we've just got so long to try this and if
9 we get into that and take all the time doing that,
10 then we'll be down there and --

11 I tend to understand what Mr. Overby is
12 telling me. What do you -- what do you say about
13 that? Is it --

14 MR. ANDERSON: It's in a different
15 context, and he knows it.

16 In the context of an MDL litigation,
17 where you have tens of thousands of cases, and you
18 have -- and that's just in the federal case, and
19 then you have state court cases that have
20 consolidated cases, it's a different ball game.
21 This is a different creature we're working with,
22 Your Honor.

23 And I know you'd probably prefer not to
24 have something that had all of this baggage with
25 it, but indeed it does --

1 THE COURT: Right.

2 MR. ANDERSON: -- and in front of
3 you is a case that is attached to a lot of other
4 cases, and so if they're going to try to create
5 the bias, fundamental fairness, making sure the
6 playing field around here is level, says yes, you
7 give them that instruction, but we should have an
8 opportunity to be able to explain what that goes
9 to, so that the jury gets the full story, Your
10 Honor.

11 THE COURT: All right. I'm not --
12 hey, I'm not fussing about it. I just was making
13 a comment you may burn a lot of clock. If you
14 want to burn it, burn it. That's fine with me.
15 I'm here -- I'm here until the end of the 23rd.
16 If you can make it work, make it work. But I do
17 think they're entitled to inquire on the --

18 I mean, this was like a treatise she gave
19 yesterday. I mean, it's like she -- if it were a
20 law professor you had up here, "How many Hornbooks
21 have you written about this, you know, Professor?"

22 It's obvious that her knowledge extends
23 far beyond reading the decedent's medical records.
24 I don't think anybody in their right mind thinks
25 that they paid them \$88,000 to read those medical

1 records.

2 Her knowledge of this was so expansive
3 that I had to stay on it, and we -- I don't know
4 how many conversations we had up here in sidebar
5 over that, because it's pretty obvious she has
6 some pretty direct opinions, and of course those
7 are based on a number of things, one of which is
8 that she's researched this for beaucoup number of
9 cases.

10 So it's not like she just put all this
11 knowledge into the Budke case and then she's going
12 to go home and clean her computer off and start
13 over again.

14 I think you're entitled to inquire as to
15 whether her -- if she did all -- if she did all
16 that she's done for \$88,000.

17 MR. BALL: Well, Your Honor --

18 THE COURT: How do you -- okay.
19 Tell me how you want to --

20 MR. BALL: Well, I mean, we
21 think -- we think that the -- that it should be --
22 just like David Overby said, that it should be a
23 situation where -- and I've encountered this with
24 recurrent experts all the time, and "How much has
25 this law firm paid you" --

1 THE COURT: Yeah.

2 MR. BALL: -- and then that
3 doesn't allow them to come in and talk about all
4 the other cases, you know, that -- that are out
5 there.

6 And just because there is an MDL doesn't
7 change that. You're entitled to talk about the
8 bias of a witness as it relates to payments from a
9 lawyer and the fact that that's -- this is her
10 only job is working for this lawyer.

11 MR. SLATER: That's actually not
12 accurate, though. She does do other things, Your
13 Honor. They can ask her that. We're not trying
14 to stop them from asking the question.

15 MR. BALL: She testified that this
16 is her only source of income, okay? So --

17 But if we do that, what we don't want to
18 do is turn around and hear about other cases,
19 because you've ruled that out, so that's why we're
20 having this discussion, and it's obvious it's
21 appropriate we're having this discussion.

22 THE COURT: Well, what has sen --
23 is there any way she can pare down that amount?
24 Because I mean otherwise, if they say, "Well,
25 she's gotten \$5 million" or 1 million or

1 whatever -- 50 cents, whatever the number is,
2 then, you know, it sounds like, "My God, they have
3 spent a million dollars in testimony on this
4 case."

5 MR. SLATER: We just want to tell
6 the jury the truth. If they want to ask the
7 question, she should be allowed to tell the truth
8 in response. That's all we want to do.

9 MR. BALL: If they can talk about
10 how much money she's spent reviewing all the
11 documents and doing the 500-page report without
12 reference to the other cases -- okay? -- give us
13 that number.

14 MR. SLATER: Mr. Ball, I don't
15 know what we're going to do. We can't make up a
16 new reality.

17 MS. GUNN: Open is open. If they
18 want to talk about it, we get to talk about it.

19 MR. SLATER: She's under oath to
20 tell the truth.

21 MS. GUNN: It's their choice.

22 MR. SLATER: Yeah. We're not
23 going to lie to the jury.

24 MS. STRAUSS: It's a Hobson's
25 choice, Your Honor. That's not an appropriate

1 choice.

2 We're suggesting one question and one
3 answer that doesn't open up an entire scope and
4 allows us to do what is required under Missouri
5 law on bias.

6 As you can imagine, almost a million
7 dollars, or whatever number they want to come up
8 with --

9 THE COURT: Yeah.

10 MS. STRAUSS: -- that doesn't
11 reference these six other cases that she reviewed,
12 is a substantially higher number than the 88,000
13 they offered yesterday, and right after that, they
14 went into this long list of the hundreds of
15 thousands of documents of depositions and
16 consultants.

17 THE COURT: All right. Here's
18 what I'm going to do and I may commit an error
19 right here and if I do, well, that's -- you know,
20 me bad and I'll learn something from it.

21 I'll let you ask that question and I'll
22 let you ask three repair questions, but we're not
23 going to get into the MDL litigation --

24 MR. BALL: What would the three
25 be, though?

1 THE COURT: What?

2 MR. BALL: What would the repair
3 questions be?

4 MS. GUNN: Open is open.

5 THE COURT: Gosh, I don't know.
6 Huh?

7 MS. GUNN: Open is open. If they
8 want to talk about it, then we get to respond, or
9 we leave it as it is.

10 MS. STRAUSS: Your Honor, it
11 requires a --

12 THE COURT: But the 88,000 is not
13 a true figure.

14 MR. SLATER: Well, but I phrased
15 it as "How much money have you been paid for the
16 work you've done specifically in this case?" And
17 I -- and we can put the transcript in front of --

18 MS. STRAUSS: And right after that
19 you spent all this time talking about the other
20 things --

21 MR. SLATER: Well, I did, but the
22 jury was --

23 Look, I told -- nothing was misleading.
24 I said she was paid 88,000 in this case. That's a
25 truthful statement.

1 And then I said, "Let's talk about all
2 the things you've done in general," and we went
3 through it. I didn't ask how much she's been paid
4 for that.

5 I'd welcome them to say, "And for all
6 that other work, you've been paid, about -- you
7 know, close to a million dollars," or whatever the
8 number is. And I don't even know. I'm afraid to
9 ask my bookkeeper. But whatever it is.

10 And then Dr. Weber should be able to say,
11 "Yes, I have, and, you know, this is what I'm
12 doing it for and this is the context," and then
13 the jury hears the truth.

14 MS. STRAUSS: Judge --

15 MR. SLATER: I've never had
16 actually, in my career, an argument like this
17 where someone is trying to set up their cross on
18 bias of my expert to say, "Look, we're going to
19 impeach their expert. We don't want the expert to
20 be able to tell the truth about what he or she
21 did."

22 I don't -- I think we're just burning
23 time here. I don't think they're going to do it.
24 I think it's going to be two questions or three
25 questions total, anyway, because they don't want

1 to go there because they don't want to open the
2 door and Hobson's choices happen all the time and
3 we always have to weigh things.

4 MS. STRAUSS: Judge --

5 MR. SLATER: That's the hard thing
6 of being a trial lawyer.

7 MS. STRAUSS: Judge, there are two
8 different standards that apply here. It is not
9 error for you to allow us to put her number in to
10 show bias without addressing the standard of other
11 cases which have to be substantially similar and
12 all of the other standards that apply.

13 It's one question and answer. It's also
14 curative of what they did yesterday and it does
15 not open the door.

16 MR. ANDERSON: Your Honor, they
17 want it both ways and it's not fair. If they want
18 to come in and say that, as Your Honor has pointed
19 out, we have a chance to rebut it. That's what's
20 fair.

21 MR. SLATER: She's under oath --

22 MR. ANDERSON: Night does follow
23 day.

24 THE COURT: Well, what I fear is,
25 though, we'll go beyond fair and just get -- we'll

1 make a case within a case over what all she's
2 doing, and I don't want to get into that.

3 MR. SLATER: It's up to them.

4 MR. BERGMANIS: If they open the
5 door --

6 MR. SLATER: We're not saying they
7 can't ask about bias. We just want her to tell
8 the truth. When she's on the stand under oath,
9 she just wants to tell the truth. That's all.

10 MR. BALL: It's not error for you
11 to rule that we're entitled to look into bias,
12 which is totally proper under the rules, and it
13 would be error to say that that opens the door to
14 dozens or hundreds or thousands of other lawsuits.
15 That's where we are.

16 MR. ANDERSON: But that's not --
17 yeah, but that's not what we said that we want to
18 do.

19 They make these broad sweeping arguments
20 and they're not specific.

21 THE COURT: Let's just do this:
22 Let's just go ahead and play the tune and I'll
23 tell you when I've heard all of it I want. Okay?

24 MR. BALL: But are you going to
25 let them ask questions --

1 I mean, we need to know this because --

2 MR. SLATER: We're not conducting
3 your cross, so --

4 MR. BALL: Excuse me. Will we be
5 -- if we say something about the amount of money
6 she's been paid, will they then be allowed to ask
7 anything about other lawsuits?

8 Because if they are --

9 MR. SLATER: Depends what you ask,
10 how you ask it, sir.

11 MS. STRAUSS: Right. The reason
12 for asking for a ruling now, Your Honor, is that
13 that is not going to be appropriate in this case
14 and we don't want to do that, but we think we're
15 entitled to --

16 THE COURT: Well, depending on
17 what she says, but I don't want to open the door
18 on this thing, but I think we've got -- we've got
19 to know that there -- something happened to cause
20 her to do all the work that she's done for the
21 amount of money that she's --

22 MR. BERGMANIS: She should be
23 allowed to testify truthfully. She's going to be
24 -- she's a medical doctor. She's under oath.

25 THE COURT: Hey, if she's under

1 oath and she says, "This is what I got," okay,
2 asked and answered. All right?

3 MR. BERGMANIS: And if asked,
4 "What did you get paid all this money for," she
5 needs to be able to tell truthfully what work she
6 did.

7 MS. STRAUSS: We're not going to
8 ask her that question.

9 THE COURT: Okay. Let's --

10 MS. STRAUSS: We're just going to
11 ask her what she's been paid --

12 THE COURT: Okay. Let's --

13 MS. STRAUSS: -- by Mr. Slater's
14 firm.

15 THE COURT: All right. All right.

16 MR. SLATER: Okay. We're good.

17 THE COURT: All right. We're
18 good. I think. Anyway, we may be back up here,
19 but --

20 MR. HYDE: Sorry about the time,
21 Judge.

22 THE COURT: That's all right.

23 MR. SLATER: You're the master of
24 your question, and once the question comes out,
25 you don't control it anymore.

1 THE COURT: There you go.

2 Let's bring the jury up.

3 MR. BALL: Your Honor, I still
4 don't understand. I want to make sure we
5 understand.

6 MR. SLATER: Oh, come on.

7 MR. BALL: I still don't
8 understand. I still don't understand. Just one
9 question I've got.

10 THE COURT: Yeah.

11 MR. BALL: If we ask the
12 question -- if we ask the question "Have you been
13 paid almost a million dollars by Mr. Slater's
14 firm," are they going to be allowed to ask
15 questions about other lawsuits that she's worked
16 on? That's the question I have.

17 We have to know that before -- because I
18 don't want to ask --

19 THE COURT: Unless you ask --
20 unless you ask it -- "Have you gotten a million
21 dollars to do what you're doing in this case?"

22 MR. BALL: No, that's not what
23 we're going to -- what now?

24 THE COURT: I don't know. Just
25 ask it and we'll get into it when it comes. I

1 don't know what to tell you.

2 MR. BALL: Yeah.

3 THE COURT: I think it's beyond my
4 pay grade, but, you know, I'm going to try to do
5 the right thing.

6 MR. BALL: I know you are, Judge.

7 THE COURT: I don't want to spend
8 the rest of the week litigating this thing, but I
9 think it's a fair question, "You didn't do all of
10 this for \$88,000, did you?"

11 Now, I don't know how you want to phrase
12 it.

13 MR. BALL: All right. Okay.

14 THE COURT: Maybe that's a country
15 boy way. But anyway...

16 MR. HYDE: We thought it would
17 have been a good idea to get here at 8:30 but we
18 messed that up, I guess.

19 THE COURT: Yeah.
20 Woulda-coulda-shoulda.

21 (The following proceedings were
22 held in the courtroom in the presence of the
23 jury:)

24 THE COURT: Good morning.

25 JUROR: Good morning.

1 THE COURT: Well, we're off a
2 little but maybe we're getting closer. Keep
3 hoping.

4 JUROR: Good morning.

5 THE COURT: Good morning.

6 JUROR: They took our water.

7 THE COURT: Somebody missing
8 water?

9 JUROR: Yeah. They took our
10 water.

11 THE BAILIFF: All present and
12 accounted for.

13 Court's back in session.

14 THE COURT: All right. Be seated.

15 Let's see. You had completed your direct
16 testimony of the doctor, correct?

17 MR. SLATER: Yes, Your Honor, and
18 I believe Ms. Jones began her cross --

19 THE COURT: Yeah, she did.

20 MR. SLATER: -- and Dr. Weber is
21 ready to step back up and continue her testimony.

22 THE COURT: Is it all right that I
23 just remind her of the oath that she took or do
24 you want me --

25 MS. JONES: Absolutely.

1 THE COURT: -- to re-swear her?

2 Okay. Come on up.

3 THE WITNESS: Thank you.

4 THE COURT: I'm sure you've been
5 in courts enough times to know that that oath
6 follows you around kind of like your shadow.

7 THE WITNESS: Yes, Your Honor, I
8 do.

9 THE COURT: All right. Then you
10 may stand.

11 I started to say "You may be seated," but
12 you may stand.

13 THE WITNESS: Thank you.

14 THE COURT: Yes.

15 DR. ANNE WEBER,
16 called as a witness on behalf of the Plaintiff,
17 being previously sworn by the Court, testified:

18 CROSS-EXAMINATION (Cont'd)

19 QUESTIONS BY MS. JONES:

20 Q. Good morning, Dr. Weber.

21 A. Good morning.

22 Q. Dr. Weber, we were talking about
23 yesterday, before we stopped, that you had not
24 previously implanted -- never implanted a Prolift.
25 Correct?

1 A. Yes, that's right.

2 Q. You've never removed a Prolift?

3 A. That's right.

4 Q. Never examined a woman that had a
5 Prolift?

6 A. That's right.

7 Q. And I think you told us that you had
8 never attended or seen any of the professional
9 education programs that Ethicon produced for
10 doctors.

11 A. Yes, that's right.

12 Q. Now, yesterday you showed us a video --
13 an animation and a video of surgery. You remember
14 that?

15 A. Yes. That's Ethicon's training video.

16 Q. And there's one thing I want to clear up.
17 That's -- that video and that animation
18 is also something you had never seen before you
19 were hired by Mr. Slater, correct?

20 A. Yes, that's right.

21 Q. And you showed the jury two different
22 parts of that video. One was an animation and one
23 was part of the actual surgery. You remember
24 that?

25 A. Yes.

1 Q. And just to make sure that we all
2 understand, all of that was part of the
3 professional education program that Ethicon
4 produced. Correct?

5 A. Those were training videos produced by
6 Ethicon. They were not used in the professional
7 education courses that Ethicon provided.

8 Q. Some of those --

9 Well, those videos, including the actual
10 surgery video, were materials provided by Ethicon
11 to doctors. Correct?

12 A. Yes, that's correct.

13 Q. So I just want to make sure that the jury
14 understands that the actual surgery that you
15 showed was also something that Ethicon produced
16 and gave to doctors so they could see how the
17 procedure should be done. Correct?

18 A. Yes, that's correct.

19 Q. Now, you told us yesterday that you had
20 begun working on this case I believe in January of
21 2010?

22 A. No. I began working with Mr. Slater in
23 January of 2010.

24 Q. And --

25 A. That's five years now.

1 **Q. And since that time, you went through and**
2 **you looked at a bunch of documents?**

3 A. Yes. Hundreds and thousands of
4 documents.

5 **Q. And you looked at those hundreds and**
6 **thousands of documents so that you could educate**
7 **yourself about the Prolift?**

8 A. I reviewed those documents so that I
9 could learn what Ethicon knew and withheld from
10 the public.

11 MS. JONES: Objection, Your Honor.

12 I --

13 THE COURT: Sustained.

14 MS. JONES: I'd ask the jury to
15 disregard.

16 THE COURT: Please disregard that
17 statement. There will be more questions.

18 **Q. (By Ms. Jones) At the time that you**
19 **started working with Mr. Slater in 2010, you had**
20 **not seen any of the professional education**
21 **programs from Ethicon?**

22 A. I had not attended professional education
23 that Ethicon sponsored, that's correct.

24 **Q. In fact, I believe that you told us that**
25 **you actually didn't perform surgery after 2004.**

1 **Is that correct?**

2 A. Yes, that's correct, because of my
3 medical condition.

4 **Q. And you last saw a patient in 2005, is**
5 **that correct?**

6 A. No, that's not correct. That was -- I
7 was forced to discontinue my medical practice in
8 2006.

9 **Q. And you've not seen a patient since 2006?**

10 A. That's right.

11 **Q. You're not licensed to practice medicine**
12 **in any state in the United States today, are you?**

13 A. That's right. I'm not --

14 **Q. You haven't --**

15 A. -- caring for patients, so there isn't a
16 need for me to be licensed.

17 **Q. And you haven't attended any type of**
18 **continuing medical education programs in the last**
19 **few years, have you?**

20 A. In the two years, yes, that's correct.
21 My health has --

22 **Q. And so --**

23 A. -- prohibited me from traveling
24 extensively.

25 **Q. In the course of reviewing those**

1 documents, you have an hourly fee you're charging?

2 A. Yes, that's correct.

3 Q. And that's \$350 for reviewing documents?

4 \$350 per hour?

5 A. That's the number -- figure that's
6 currently correct, yes.

7 Q. And you're charging a thousand dollars
8 per hour for testifying here today?

9 A. Yes, that's correct.

10 Q. Now, you told us yesterday -- and I think
11 it's self-evident, but you told us yesterday that
12 you'd been board certified in obstetrics and
13 gynecology?

14 A. Yes, that's right.

15 Q. You were not ever board certified in the
16 subspecialty of female reconstructive and pelvic
17 surgery, were you?

18 A. No. That's right. That wasn't available
19 at the time when I was in clinical practice.

20 Q. And when that board became available, you
21 didn't sit for that board, did you?

22 A. No. I was not in clinical practice at
23 that time.

24 Q. It is true that you are no longer board
25 certified in any field, are you?

1 A. That's correct. Since I'm not in
2 clinical practice, that's not something that's
3 required of me.

4 Q. You told us yesterday that you had been a
5 peer reviewer of certain medical articles. You
6 remember that?

7 A. Yes, that's correct.

8 Q. And I'd like to talk with you a little
9 bit about peer review.

10 My understanding is that what you told us
11 yesterday was that the process of peer review is
12 one to assure, if you can, the scientific and
13 medical validity of the articles that appear in
14 the medical journals. Correct?

15 A. Yes, that's right.

16 Q. And what happens is that somebody that's
17 conducted a study, for example, submits that study
18 to a particular journal for publication. Correct?

19 A. Yes, that's right.

20 Q. And the editorial board then looks at
21 that study to determine whether or not, on its --
22 on its face, it appears to be something that the
23 journal would be interested in publishing.
24 Correct?

25 A. The editor, yes.

1 Q. The editor does.

2 And then if the editor thinks that it
3 looks like a good piece of information to be
4 published in the scientific literature, the editor
5 will send it out to peer reviewers who haven't had
6 anything to do with the particular study to review
7 the article and the materials submitted. Correct?

8 A. To review the manuscript, yes.

9 Q. And then they may make suggestions about
10 changes or raise questions about the information
11 that's contained in there, correct?

12 A. Yes, that's right.

13 Q. And sometimes it is sent back then to the
14 editors with a suggestion that changes be made?

15 A. The reviewers' comments are sent back to
16 the editor, yes.

17 Q. And the editor makes a determination as
18 to whether or not the reviewers believe that the
19 data contained in the scientific article is
20 accurate and good for publication?

21 A. The comments go back to the author, but I
22 think what you're saying is that the editor makes
23 the final decision as to whether the manuscript is
24 accepted.

25 Q. Well, that, but first, generally the

1 comments go back to the editor, who makes a
2 determination about whether or not we're going to
3 reject it right now or whether we're going to send
4 it back to the author to make corrections.
5 Correct?

6 A. No, that's not my experience.

7 Once it's been sent to peer review to be
8 reviewed by these other people in the field, the
9 editor sends those comments then to the author.

10 Q. And the author can either accept those
11 changes and make some changes and send it back to
12 the editor or not. Correct?

13 A. Yes.

14 Q. And the editor then makes a determination
15 about whether or not to accept that particular
16 study or article for publication?

17 A. The manuscript, yes.

18 Q. And the editor sometimes will send that
19 particular piece of information or particular
20 study back out a second time to peer reviewers to
21 look at, correct?

22 A. That does happen sometimes, yes.

23 Q. And then the editor, after he's gotten
24 all of these independent reviews and comments from
25 the author, makes a determination as to whether or

1 not it ought to be published. Correct?

2 A. Yes, that's correct.

3 Q. And the intent of doing all of that is to
4 see that the studies as published in the public --
5 in the professional medical and scientific
6 literature are as accurate as possible?

7 A. Yes. The process relies on the honesty
8 of the authors who are presenting --

9 Q. Well --

10 A. -- this information to --

11 MS. JONES: Excuse me, Your Honor.

12 A. -- the journal.

13 THE COURT: Just a minute.

14 Q. (By Ms. Jones) Dr. Weber, my question
15 was very simple.

16 The purpose of the peer review process is
17 to establish and to ensure the scientific and
18 medical accuracy of the literature that's
19 published as best as possible, correct?

20 A. No, that's not quite true, because what
21 the peer reviewers and the editors receive is only
22 the manuscript. The editor can request the data
23 behind a study in particular, but that's not
24 typically done.

25 So as I said, the whole process relies on

1 the scientific honesty of the authors.

2 Q. And, Doctor, let me ask you this
3 question: You showed the jury some analysis
4 yesterday of the French TVM data.

5 Do you remember that?

6 A. Yes, I do.

7 Q. That's analysis that you did that's not
8 been subject to peer review, has it?

9 A. No. That's an independent analysis that
10 I carried out.

11 Q. All right.

12 A. And in addition, the data were
13 independently reviewed by a biomedical
14 statistician --

15 MS. JONES: Objection, Your Honor.

16 A. -- who --

17 THE COURT: Sustained. It's not
18 responsive.

19 MS. JONES: I would ask that the
20 jury be instructed to disregard the comment --

21 THE COURT: All right. Disregard
22 that last soliloquy and we'll start over again.

23 MR. SLATER: Your Honor, can I
24 briefly approach you for one second to ask a quick
25 question?

1 THE COURT: Why, sure.

2 MR. SLATER: Quick question. I'm
3 going to jog.

4 THE COURT: Well, you don't have
5 to jog, but --

6 (Counsel approached the bench and
7 the following proceedings were held outside the
8 hearing of the jury:)

9 MR. SLATER: Judge, I understand
10 that Ms. Jones wants to ask questions and try to
11 limit the answers, but she's asking some questions
12 and I'd appreciate if she asks a question that
13 makes a suggestion that Dr. Weber wants to
14 truthfully answer it, that she not be cut off,
15 because it was misleading to say no one else has
16 reviewed the data because she knows that a
17 biomedical statistician came to all the same
18 conclusions that is a nationally known biomedical
19 statistician.

20 So if she's going to ask that question,
21 again the jury should know. I don't want them to
22 be misled. I'd rather she not cut off answers.
23 She couldn't go there because she knows the
24 answer. That's all I want to say.

25 MS. JONES: May I just simply say,

1 one, the question didn't call for that. The
2 question simply asked whether or not it had been
3 submitted to peer review.

4 MR. BALL: Yeah.

5 MS. JONES: Secondly -- secondly,
6 Your Honor, she wants to talk about another expert
7 that Mr. Slater hired to look at this. Now,
8 that's totally improper.

9 MR. SLATER: I'll listen to the
10 questions and I'll wait for redirect.

11 THE COURT: Okay.

12 MR. SLATER: I just would like her
13 not to cut her off.

14 MS. JONES: No. That's not
15 appropriate, Your Honor.

16 MR. BERGMANIS: Don't ask the
17 question.

18 MS. JONES: I'm entitled to get an
19 answer to my questions.

20 THE COURT: All right. Let's try
21 that approach. I'll listen real carefully to your
22 question, and if I think she's going beyond that,
23 I'll cut her off.

24 MR. SLATER: Thanks, Judge.

25 MS. JONES: Thank you.

1 (The proceedings returned to open
2 court.)

3 Q. (By Ms. Jones) Dr. Weber, we're going to
4 come back and talk about this, but the French
5 doctors that were members of the transvaginal mesh
6 group, the nine doctors that were members of that,
7 you're familiar with that?

8 A. Yes, I am.

9 Q. And you're familiar with the fact that
10 they have, in fact, published the results of their
11 study?

12 A. Yes.

13 Q. And those documents have been published
14 in well-recognized medical journals and scientific
15 journals?

16 A. Well, that's exactly what I was referring
17 to as far as the process relying on the
18 scientific --

19 MS. JONES: Objection, Your Honor.

20 A. -- honesty because as we saw yesterday,
21 when I reviewed the data independently --

22 MS. JONES: Excuse me.

23 THE COURT: Just a minute.

24 Q. (By Ms. Jones) Dr. Weber, my question --

25 THE COURT: Just answer the

1 question, if you can.

2 Q. (By Ms. Jones) -- was very simple.

3 Did the doctors from the TVM group
4 publish their scientific data in peer-reviewed
5 journals?

6 A. To answer that question simply with a yes
7 or no would be misleading, and what I'd like to
8 convey to the jury is exactly why that's true.

9 MS. JONES: Well, Your Honor --

10 THE COURT: I'll let her answer,
11 and then if it's -- if it's going beyond the
12 bounds of what we're talking about here, and that
13 is, whether it was ever peer-reviewed or not --

14 MS. JONES: That was the question.

15 THE COURT: That's the question.
16 I mean, either you know it or you don't know it.

17 THE WITNESS: I do know that it
18 was peer-reviewed. And as I said, it relies on
19 the scientific honesty of the authors and that is
20 in question, as -- based on my review of the data.

21 THE COURT: Well, all right. Wait
22 a minute.

23 Now, not your opinion of this. She just
24 asked you a question: Was it reviewed?

25 I understand you've got a totally

1 different outlook on it, but you'll get an
2 opportunity to talk about that, I'm sure, on
3 redirect.

4 Q. (By Ms. Jones) You've already talked
5 about that on direct, have you not?

6 A. We reviewed some of that yesterday. We
7 weren't able to review all of it.

8 Q. There have been many different articles
9 published by the members of the French
10 transvaginal mesh group, correct?

11 A. Yes, they [sic] have.

12 Q. Now, I want to switch around and I'm
13 going to skip around just a little bit because I
14 want to make sure that we cover some things
15 yesterday before I want to talk -- that you talked
16 about yesterday.

17 You remember that you talked about your
18 ACOG publication?

19 A. Yes.

20 Q. And as I appreciate it, you're concerned
21 because the word "experimental" was deleted from
22 that practice bulletin. Correct?

23 A. Yes, that's right.

24 Q. And you spent time yesterday going over
25 and reading your letter to the editor complaining

1 **about that, correct?**

2 A. The letter to the editor was published to
3 convey to the scientific community what happened
4 behind the scenes.

5 **Q. And you published that letter to the**
6 **editor in 2009, correct?**

7 A. The journal published that letter, yes.

8 **Q. And the change was actually made in 2007,**
9 **wasn't it?**

10 A. Yes, that's correct.

11 **Q. In fact, that change was made six months**
12 **after -- six months after the original publication**
13 **with your word "experimental" in it, correct?**

14 A. Yes. That's unprecedented in the history
15 of ACOG practice bulletins to have a change made
16 in such short order.

17 **Q. And in fact, in response to your letter**
18 **in 2009, the ACOG published a response about how**
19 **that was handled, didn't they?**

20 A. Yes, they did.

21 **Q. And when they did that, they published**
22 **and they made it clear that that change had gone**
23 **through the same channels, did they not?**

24 A. The same channels prompted by industry
25 influence.

1 Q. Well --

2 A. Ethicon, specifically.

3 Q. -- there's nothing in the --

4 ACOG never said it was due to industry
5 influence, did it?

6 A. ACOG didn't have the full story and --

7 Q. Whoa.

8 MR. SLATER: Excuse me.

9 A. -- Ethicon withheld that information from
10 the public.

11 MR. SLATER: Excuse me. I would
12 ask that the witness, Dr. Weber --

13 THE COURT: Just a minute. What?

14 MR. SLATER: I'm sorry. I just
15 would ask that if Dr. Weber is speaking, that she
16 be allowed to finish her answer, as opposed to
17 being interrupted.

18 MS. JONES: I think I'm asking her
19 to answer my question.

20 THE COURT: As long as she doesn't
21 go far afield from what she's asking, I'll go
22 along with that, but I'm not going to have her
23 pontificate on things she wasn't asked.

24 MR. SLATER: I understand. But
25 she was answering that question, I believe, and in

1 fairness, I'd just like her to let her speak.

2 THE COURT: All right.

3 Q. (By Ms. Jones) The question was: When
4 ACOG published the letter, ACOG said it was in
5 response specifically to numerous calls and emails
6 by physicians doing the surgery, did it not?

7 A. It was a small number of physicians.

8 Q. And when ACOG published the response,
9 ACOG said that when they got a number of the
10 complaints, that they sent the practice bulletin
11 back through the same standard channels to
12 evaluate whether or not it should be changed,
13 didn't it?

14 A. What I was told was that --

15 Q. I'm -- I'm asking you --

16 A. -- the committee --

17 Q. -- Dr. -- Dr. Weber --

18 A. I'm explaining what channels you're
19 referring to.

20 Q. I'm asking you whether or not --

21 MR. SLATER: Your Honor, I would
22 ask that she be allowed to answer --

23 THE COURT: Just -- all right.

24 Wait a minute. Whoa.

25 Reask your question and I'm going to try

1 to listen to every word of it, because I think
2 what you were asking her and what she was
3 answering, it was apples and oranges, and I'd like
4 to at least -- let's either talk about apples or
5 oranges.

6 Q. (By Ms. Jones) When ACOG published the
7 response --

8 You're familiar with their response,
9 aren't you?

10 A. Yes, I am.

11 Q. And when ACOG published their response,
12 ACOG specifically noted that when the practice
13 bulletin that you published with the word
14 "experimental" was published, that the college,
15 the American College of Obstetrics and
16 Gynecology --

17 That's the group you were a member of,
18 correct?

19 A. The American College of Obstetricians and
20 Gynecologists, yes.

21 Q. And that's a group of professional
22 doctors that treat women?

23 A. Yes, it's a professional organization.

24 Q. -- that when the practice bulletin that
25 you wrote was published, that the college received

1 emails, letters, and phone calls from ACOG fellows
2 who objected to the word -- use of the word
3 "experimental" to describe the anterior and
4 posterior vaginal prolapse. Correct?

5 A. They were -- this was specifically in
6 reference to the mesh kits, and they were
7 objecting not because of patient safety --

8 Q. Excuse me, Doctor.

9 A. -- but because of their concern of
10 insurance companies not paying for procedures that
11 were labeled experimental.

12 Q. Did the college specifically --

13 A. They were concerned about their income.

14 Q. Did the college specifically say that
15 their concern centered on the ambiguity of the
16 word "experimental" and their perception that
17 "experimental" did not accurately reflect the wide
18 acceptance of those surgeries?

19 A. This is exactly the issue.

20 Q. Look, I'm just asking you, Doctor: Is
21 that what the American College of Obstetrics and
22 Gynecology published?

23 Is that what they said?

24 A. That's what they said.

25 Q. Now, did they also say that the college

1 followed the routine procedure for handling such
2 correspondence by putting the -- that -- the
3 agenda on -- the matter on the agenda for the next
4 college -- the next meeting of the committee on
5 practice bulletins, gynecology?

6 A. Yes. That's what I was trying to explain
7 as far as the --

8 Q. And then --

9 A. -- usual channels that you referred to.

10 Q. And then, Doctor, that as a result of
11 that meeting, that practice bulletin was changed
12 and that practice bulletin was changed by, one,
13 initially, the committee on practice bulletins for
14 gynecology, correct?

15 A. Yes.

16 Q. And then it was subsequently presented to
17 certain of the staff of the American College of
18 Obstetrics and Gynecology?

19 A. I believe the committee approved the
20 document and then it went to the board.

21 Q. And then it was approved by the executive
22 board for publication. Correct?

23 A. Yes.

24 Q. And the executive board for publication
25 were doctors who practice in the field of

1 **obstetrics and gynecology from around the**
2 **United States. Correct?**

3 A. Yes, that's true.

4 Q. One other thing and then we're going to
5 **get to some different issues.**

6 You were asked yesterday about some
7 **documents relating to UltraPro. Do you remember**
8 **that?**

9 A. Yes.

10 Q. And so we can remind the jury, UltraPro
11 **is a mesh that contains -- this is just my**
12 **words -- a combination of Gynemesh PS and a**
13 **partially absorbable mesh. Correct?**

14 A. Yes. UltraPro is another hernia mesh
15 that was, as you say, a combination of a permanent
16 component, the polypropylene, and an absorbable
17 component.

18 Q. And that was a mesh that was evaluated by
19 **Ethicon for use in the Prolift kit, and we've seen**
20 **other discussions about it, correct?**

21 A. Later. You mean much later, after the
22 Prolift had been marketed?

23 Q. In the mid-2005, '6, '7. That area.
24 **Mid-2000s.**

25 Let me just -- I don't want to confuse

1 **this. This is not where I'm going.**

2 **The fact of the matter is, you know that**
3 **UltraPro was considered as a potential use in**
4 **Prolift, correct?**

5 A. It was considered and not fully evaluated
6 when Ethicon put Prolift on the market as just the
7 Gynemesh PS mesh itself.

8 Q. Now, I want to make sure that we're clear
9 about something. This is -- I just have one
10 question about this.

11 A. Uh-huh.

12 Q. As a practical matter, you don't believe
13 there is a single mesh of any type that can be
14 used appropriately transvaginally, do you?

15 A. None of the meshes that were available
16 were safe for transvaginal use. That's right.

17 Q. And what you have testified to, just so
18 we're clear and everybody knows, is that you
19 cannot tell us of any mesh that you believe -- you
20 believe -- can be appropriately used
21 transvaginally.

22 A. As I said, of the meshes that were
23 currently available, none of them have proven to
24 be safe for use in transvaginal implantation.

25 Q. And what you have said and testified to

1 is that you don't believe any mesh product exists,
2 correct?

3 A. That's right. Currently, no mesh product
4 exists that is safe for use in the vagina.

5 Q. And now --

6 A. Ethicon itself said there is no
7 patient-centric -- pelvic-floor-centric material.

8 Q. Now, you've testified to that, and that
9 would include, in your judgment, UltraPro?

10 A. As far -- to --

11 My information, gathered from my review
12 of the internal Ethicon documents and the studies
13 that have been published to date as to use of
14 UltraPro in the Prolift kit, is that is unsafe.

15 Q. Now, so that when you came in here and we
16 were talking about those documents yesterday, you
17 didn't mean to convey to the jury that you thought
18 that because -- well, let me strike that.

19 Let me go back and let's talk about this
20 case a little bit.

21 We've talked about a number of things
22 about the development of Prolift and a number of
23 things that you had said. Let's see if we can go
24 back to the history.

25 And you remember yesterday you were asked

1 by Mr. Slater and you showed Mr. Slater a number
2 of -- discussed with Mr. Slater a number of
3 studies regarding recurrence rate of the more
4 traditional native tissue surgeries?

5 A. Yes.

6 Q. And there was some discussion, if you
7 remember, that back in the 1990s, for example, and
8 the early 2000s there was significant concern
9 about recurrences of prolapse in women who had
10 prolapse surgery, correct?

11 A. Yes. At that time, the availability of
12 questionnaires -- the questionnaires weren't
13 available and the outcomes focused mainly on the
14 anatomic -- the position of the organs, rather
15 than how the women were feeling.

16 Q. Doctor, I didn't ask you anything at all
17 about questionnaires, did I?

18 A. Well, you were asking about the --

19 Q. My question is --

20 A. -- outcomes that had been reported.

21 Q. -- did I ask you anything at all about
22 questionnaires?

23 A. I was doing the best I could to answer
24 your question.

25 Q. Well, let's -- let's see if we can try

1 again.

2 A. Okay.

3 Q. There were a number of publications in
4 the late 1990s and early 2000s where doctors
5 were expressing concerns about the recurrence rate
6 of prolapse in women who had had native tissue or
7 traditional surgeries without mesh, correct?

8 A. Yes, that's correct.

9 Q. And among those articles that were
10 published were articles that, for example, you
11 published showing a 30% recurrence rate?

12 A. Well, again, this is where answering that
13 with a simple yes or no --

14 Q. I'm asking the question, Doctor --

15 A. -- would be misleading.

16 Q. -- very simply: Did you accomplish a
17 study in 2001 that said there was a 30% recurrence
18 rate in anterior colporrhaphy?

19 A. Based only on the anatomic position of
20 the organs and not how the -- how the women were
21 feeling, yes, that's right.

22 Q. All right. And you similarly published
23 in 2004 another study that suggested that there
24 was a 58% recurrence rate, correct?

25 A. Yes. Based on the position --

1 Q. And --

2 A. -- of the organs and not how the -- on
3 the women were feeling.

4 Q. And when they were looking at the
5 position of the organs at that point in time,
6 that's what doctors were looking at to determine
7 whether or not there was a recurrence rate.
8 Correct?

9 A. That's what doctors were looking at.

10 Q. And --

11 A. That's not the outcome of greatest
12 importance to women.

13 Q. And so that we're clear, Doctor, when
14 we're talking about a recurrence rate, we're
15 talking about a failure of the original surgery to
16 cure prolapse. Correct?

17 A. No, I don't agree with that.

18 "Failure" implies -- a failure is when
19 women do develop a recurrence to the extent that
20 they require treatment or become symptomatic. A
21 recurrence simply means that the anatomic position
22 of the organs is in an arbitrary stage that
23 doctors have decided means that it's not perfect.

24 Q. It is fair to say, Doctor, that the
25 medical community was concerned about the

1 recurrence rate of prolapse in the late 1990s
2 and 2000s because they didn't believe that the
3 surgeries were effective long-term to cure
4 prolapse. Correct?

5 A. No, I don't agree with that.

6 Q. All right. Fine.

7 Do you remember that it was, in fact, the
8 concern about failure rates that led surgeons to
9 use synthetic mesh in prolapse surgery?

10 A. That concern, propagated by Ethicon, was
11 based on a misinterpretation and a misreporting --

12 MS. JONES: Object.

13 A. -- of the medical literature.

14 THE COURT: That is not responsive
15 to the question.

16 MS. JONES: And I would ask that
17 the jury be instructed to disregard.

18 THE COURT: All right. Disregard
19 that. It didn't ask about any particular type;
20 just asked about the devices.

21 Q. (By Ms. Jones) Now, Doctor, I'm going to
22 ask the question again.

23 In the late 1990s and early 2000s,
24 doctors -- well, let me go back actually before
25 that.

1 You would agree with me that prolapse can
2 be very problematic for some women?

3 A. It can be when it's in its severe stages.

4 Q. And --

5 A. That's not what we're talking about with
6 Mrs. Budke.

7 Q. And you would agree --

8 You would agree that women are entitled
9 to have effective treatment for pelvic organ
10 prolapse, correct?

11 A. That's a goal, yes.

12 Q. And surgeons have been trying to treat
13 that condition for decades. Years and years and
14 years. Correct?

15 A. Yes, that's correct.

16 Q. And surgeons noticed, over a period of
17 time, that some women's prolapse came back.
18 Correct?

19 A. Yes, that's true.

20 Q. And they came back, at least in part,
21 because what was happening was that surgeons were
22 stitching up or using the native tissue, which was
23 already weakened by whatever caused the prolapse,
24 to fix it. Correct?

25 A. In part, yes.

1 Q. Because the thought was that if your --
2 the muscles that hold up the organs, or the
3 ligaments that hold up the organs, those tissues
4 are already weakened by -- whether it's age or
5 childbirth or whatever, that over a period of time
6 that prolapse comes back after it's been stitched
7 up?

8 A. That can happen. You're right.

9 Q. And because of that and because doctors
10 were seeing such high rates of that, they began to
11 use mesh to incorporate into the tissue to hold
12 the organs up. Correct?

13 A. Yes, that's a part of the -- how they
14 attempted to address that.

15 Q. And that started happening as early as
16 the 1960s, didn't it?

17 A. I'm not familiar with literature that's
18 that old, but it's certainly possible.

19 Q. Certainly by the 1970s, gynecological
20 surgeons, surgeons like you, urogynecologists, had
21 begun to use mesh to treat pelvic organ prolapse.
22 Correct?

23 A. Yes. And they found a high rate of --

24 Q. And --

25 A. -- complications.

1 Q. And those complications had been reported
2 long before 2000 and the TVM group came along,
3 hadn't they?

4 A. Yes, that's right.

5 Q. And in fact, among those complications
6 that were regularly reported in the medical and
7 scientific literature was the potential for
8 erosion. Correct?

9 A. Yes, that's correct.

10 Q. And in fact, there had been erosion rates
11 published by doctors of as high as 10 or 12% long
12 before the TVM group ever started working on what
13 became Prolift. Correct?

14 A. You're right. And those numbers were --

15 Q. And --

16 A. -- considered too high. That
17 complication rate --

18 Q. Well --

19 A. -- was considered too high, yet --

20 MS. JONES: Your Honor --

21 THE COURT: Okay.

22 A. -- what the French TVM group found was
23 rates even higher.

24 THE COURT: Just try to answer the
25 question.

1 MS. JONES: I move to strike, Your
2 Honor, and ask the jury to disregard the
3 voluntary --

4 THE COURT: Well, if -- where it
5 went beyond that into another study that was not
6 even asked about, disregard that.

7 I'd like to get this down to where we
8 can -- I'm not saying a yes/no answer, but answer
9 the question.

10 THE WITNESS: Yes, Your Honor.
11 I'm doing --

12 THE COURT: There may be a lot of
13 stuff that you know and I don't know because
14 apparently what I'm gathering here is you've spent
15 years and years in the study of this, and so on --

16 THE WITNESS: Yes, Your Honor.

17 THE COURT: -- so I understand
18 that. But try to answer the question.

19 These folks will ask you whatever they
20 want, to expand it, and I won't fuss about that
21 because they got a right to do it, but on the
22 other hand, please try to answer her questions.

23 THE WITNESS: Yes, Your Honor.

24 I --

25 Q. (By Ms. Jones) And, Doctor --

1 THE WITNESS: I am trying the best
2 I can.

3 THE COURT: All right. Good,
4 good.

5 Q. (By Ms. Jones) And, Doctor, it's fair to
6 say that you had published that anterior vaginal
7 prolapse --

8 That is what Mrs. Budke had, correct?

9 A. Yes, in the mildest form.

10 Q. And you have published that anterior
11 vaginal prolapse may recur after standard anterior
12 colporrhaphy in up to 40% of the patients.

13 You published that in 2001, didn't you?

14 A. Yes, you're right. That's the --

15 Q. And --

16 A. -- function -- the position of the
17 organs, not related to the function.

18 Q. And you published that that high rate of
19 recurrence --

20 And you would agree that that's a high
21 rate of recurrence. 40%. Correct?

22 A. That's a high rate of the position of the
23 organs. That doesn't tell us how the women are
24 feeling.

25 Q. Well, Doctor, the fact of the matter is

1 **that in 2000, 1999, 2002, that's -- that's how**
2 **doctors were measuring recurrence. Correct?**

3 A. Yes, you're right. That's because the --
4 the questionnaires that we needed, to find out how
5 the women were feeling, weren't available yet.

6 Q. **That's fine.**

7 **We have to look at the state of medicine**
8 **at the time that we're writing, correct?**

9 A. Yes, you're right.

10 Q. **And in 1999 and 1998 and 2000 when this**
11 **was being written, based upon the then-standards**
12 **applicable, they were talking -- you were talking**
13 **about a 40% recurrence rate, correct?**

14 MR. SLATER: Objection, Your
15 Honor. Can I just jog up here again to you real
16 quick? Thanks.

17 (Counsel approached the bench and
18 the following proceedings were held outside the
19 hearing of the jury:)

20 MR. SLATER: I'm just a little
21 concerned because Ms. Jones is going down a line
22 suggesting that our claims are going to be decided
23 based on medicine and science at the time it was
24 marketed, and obviously on a design defect claim,
25 we're not limited to that.

1 Strict liability design defect considers
2 all of the knowledge on the mesh at any time, so I
3 just would ask that that question -- I'm objecting
4 to that question because -- and the prior
5 question, I -- you know, I'll address it on
6 redirect and I'll address it in the charge, but I
7 didn't want to go any further down, and I try not
8 to object too much, as you can see, but -- so I
9 would object to going down that line because it's
10 obviously not consistent with the law.

11 MS. JONES: Well, Your Honor, that
12 really, frankly, was not my question at all. My
13 question is simply what she had written back
14 in 2000 --

15 THE COURT: Yes.

16 MS. JONES: -- and what the
17 standard was that she was writing about in that,
18 and she's trying to throw in all of this other
19 stuff that she's come up with later on.

20 THE COURT: That's why I've asked
21 her please just try to answer the question, and he
22 can -- he can go into whatever she's thinking.

23 I mean, it's pretty obvious, you know,
24 she's not a one-horse show on this case. I mean,
25 I think everybody's figured that out. I'd be

1 surprised if the folks over here haven't.

2 But anyway, let's just try to get

3 along --

4 MR. SLATER: Absolutely.

5 THE COURT: -- the best we can.

6 (The proceedings returned to open
7 court.)

8 THE COURT: Okey-doke.

9 Q. (By Ms. Jones) Dr. Weber, just bear with
10 me. I don't mean to be beating this horse but
11 I've got a follow-up question.

12 You wrote in 2001 that it was the high
13 rate of recurrence that had led to the addition of
14 synthetic materials like mesh to use in these
15 surgeries. Correct?

16 A. Yes. There's always room for
17 improvement. It's a matter of balancing the
18 improvement versus the complications that get
19 introduced.

20 Q. And, Doctor, what the -- many of the
21 doctors were doing at that time, in 2000 and 2001,
22 was taking and fashioning their own mesh to use it
23 to treat prolapse, correct?

24 A. A few doctors were doing that, yes.

25 Q. And those doctors were publishing those

1 results in the medical literature?

2 A. Yes, that's true.

3 Q. When the TVM group was formed, those
4 doctors were looking for a better, more permanent
5 cure for prolapse, weren't they?

6 A. The TVM group had two objectives.

7 One of them was as you stated. The other
8 was to understand why mesh erosion occurred so
9 commonly with the use of permanent mesh and was a
10 matter of such grave concern.

11 Q. And in terms of looking at and treating
12 women with prolapse, those doctors you know
13 historically watched each other do surgery and
14 compared how they were doing surgery to come up
15 with an appropriate mesh treatment for prolapse,
16 correct?

17 A. They were experimenting with the
18 materials and with the procedure, and while they
19 were in the midst of this experimentation, this
20 was obtained by Ethicon and promoted for
21 widespread commercial use.

22 Q. Well, that's --

23 A. They felt that --

24 Q. Could --

25 A. -- the mesh was not the appropriate mesh,

1 they were still very unhappy with the high rate of
2 complications that they found with use of this
3 mesh, and they told Ethicon for years that a new
4 mesh was required.

5 MS. JONES: Your Honor --

6 THE COURT: Yes.

7 MS. JONES: -- I move to strike.
8 Nonresponsive.

9 THE COURT: Well, it's not
10 responsive. I mean --

11 MR. SLATER: They're complicated
12 questions, Judge.

13 THE COURT: Yeah. Well, and she's
14 giving complicated answers. She knows a lot about
15 the subject. I know that. I've figured that out.

16 MR. SLATER: Balancing it out.

17 THE COURT: Yeah, yeah. We're
18 balancing it out okay. Now, let's just --

19 Again, I'm going to ask you one more
20 time, try to stick with the question, okay?

21 THE WITNESS: Yes, Your Honor.

22 THE COURT: Yeah.

23 Q. (By Ms. Jones) So let's stick with the
24 question.

25 When the TVM group was formed in 2000,

1 they looked at different types of meshes to use,
2 correct?

3 A. Yes.

4 Q. And --

5 A. You're right. They experimented with
6 different types of mesh.

7 Q. And they used --

8 When you say they experimented, these are
9 doctors. These are well-established
10 urogynecologist, pelvic floor surgeons doing
11 these surgeries, aren't they?

12 A. Yes. They were doing experimental work
13 with different types of meshes.

14 Q. And they were using those meshes in
15 patients that they were treating, weren't they?

16 A. Yes. They were doing experimental work
17 in patients that they were treating.

18 Q. And they've published the results of
19 those studies that they did, haven't they?

20 A. Yes, they did --

21 Q. And --

22 A. -- and that goes back to the issue about
23 scientific honesty.

24 Q. Well --

25 THE COURT: Well, let's don't get

1 into that.

2 Just answer the question, please, Doctor.

3 THE WITNESS: I am trying, Your
4 Honor.

5 THE COURT: Yeah. Okay.

6 Q. (By Ms. Jones) Ethicon began working
7 with these doctors to develop the tools for the
8 Prolift kit in 2003, correct?

9 A. Yes, Ethicon was closely involved --

10 Q. And --

11 A. -- with this group.

12 Q. And, Doctor, just so we're clear, you've
13 never used those tools in the Prolift kit, have
14 you?

15 A. No, I have not.

16 Q. Now, those doctors, those French doctors
17 that you say were conducting experimental studies,
18 continued to follow the women and to treat the
19 women that they had done surgery on for years,
20 didn't they?

21 A. Yes, they did.

22 Q. And they published their results after
23 years, didn't they?

24 A. They published their results which in --
25 on my independent analysis raised --

1 Q. Well --

2 A. -- grave concerns about what was being
3 reported and what truly happened.

4 Q. And, Doctor, you know that when Prolift
5 went on the market, despite what you have said
6 about their disenchantment with mesh, that those
7 doctors used the Prolift, don't you?

8 A. They did. And they were, in the
9 meantime --

10 Q. And in fact --

11 A. -- objecting to Ethicon --

12 MS. JONES: Object.

13 A. -- over and over again --

14 THE COURT: Hold it.

15 A. -- that they needed a new mesh.

16 THE COURT: Just a minute.

17 MR. BALL: May we approach the
18 bench, Your Honor?

19 THE COURT: Yes.

20 (Counsel approached the bench and
21 the following proceedings were held outside the
22 hearing of the jury:)

23 THE COURT: Now, let's go one at a
24 time and you raised the issue.

25 MR. BALL: Yeah. I've never seen

1 anything quite like this. This person is
2 obviously trying to be an advocate for the
3 plaintiff during cross-examination.

4 THE COURT: Well, I think it's
5 pretty obvious that she's a hired gun.

6 MR. BALL: I think she should be
7 strongly admonished to answer the question and not
8 go into other advocacy areas and things like that.
9 She should be admonished to do that.

10 THE COURT: I gave her pretty wide
11 latitude yesterday with her attorney on things,
12 and I've admonished her, but, you know, it's
13 just -- I hate to have to do it on every question.
14 She's not going to just answer the question.

15 MR. BALL: Well, when are we going
16 to be -- I guess we're not taking a break yet.

17 THE COURT: I was going to take a
18 break about a quarter of 11:00, if we can make it
19 that far.

20 MS. JONES: That's fine.

21 MR. BALL: We'd just ask that you
22 admonish her going forward not to do that.

23 THE COURT: All right. You have
24 something?

25 MR. SLATER: I always throw in

1 something.

2 THE COURT: Come on. We've got
3 some people up here. Go ahead.

4 MR. SLATER: I was just going to
5 say, I understand what they're saying, to some
6 extent, but the problem is there's a lot -- as you
7 say, there's a lot of baggage behind these
8 questions and when they're asking questions, I
9 mean if Dr. Weber can't answer with a simple yes
10 or no because there's more to it --

11 THE COURT: Well, I didn't --

12 MR. SLATER: -- she's trying to
13 say that, but there's -- there's a lot going on
14 between Ms. Jones and Dr. Weber where there's
15 implications to the questions that are not out in
16 front so that someone who really knows this area
17 would say, "Well, you know, that question is
18 really not straightforward."

19 Even though it might sound
20 straightforward to one of us, you or me, people
21 who really know this area, the question really
22 isn't so straightforward, so it's not that simple.

23 MS. JONES: I'm sorry.

24 MR. SLATER: And Ms. Jones just
25 probably needs to narrow her questions a little

1 and I think she can get what she wants.

2 THE COURT: Well, I'm sure she's
3 cotton-picking. You were.

4 MR. BALL: Here, listen to this.

5 THE COURT: Yes.

6 MR. BALL: "Did they publish their
7 results," and then she goes off on honesty and --

8 THE COURT: Yes or no.

9 MR. BALL: Don't give me any of
10 that stuff.

11 THE COURT: And it's just like
12 this, "I don't know how women were feeling."
13 That's not the question.

14 I mean, maybe that's a bad problem, but
15 the thing was it had to do with the medical
16 report. So I don't know whether they put out
17 questionnaires to them and asked them whether
18 they'd like a free donut if they sent something
19 in, but that's not the question. You can ask that
20 question.

21 MR. SLATER: Yeah, and I could say
22 Mr. Ball just gave a great example. When the
23 question is "Did they publish their results," they
24 didn't publish their results because Dr. Weber has
25 said their results are different than what was

1 published.

2 If the question was "Did they publish
3 results of the data and tell people what -- what
4 they -- did they say what results were," that's
5 one thing, but to say "their results," she's
6 saying they didn't publish their results because
7 it's different than the reality.

8 So that's what I'm saying is there's --
9 there's nuance in here.

10 THE COURT: Well, she's critical
11 of that. I don't know whether it's worthy of
12 criticism or not. I don't know. But to some
13 extent, this is kind of like that old story about
14 the day after Lincoln was assassinated and the
15 reporter come up and said, "Well, outside of that,
16 Mrs. Lincoln, how did you like the play?"

17 You know, I mean, that -- that's not very
18 responsive to the death of the 16th President of
19 the United States.

20 Okay. Let's try to do this.

21 (The proceedings returned to open
22 court.)

23 Q. (By Ms. Jones) Doctor, whether you agree
24 with their results or not, the French doctors and
25 Dr. Jacquetin and Dr. Cosson published what they

1 **considered to be the results of their studies,**
2 **correct?**

3 A. Yes, they did. And they were very --

4 **Q. And --**

5 A. -- concerned that in the literature they
6 published things like --

7 MS. JONES: Your Honor --

8 A. -- "Fails to fulfill obligation" -- I
9 mean, excuse me, "expectations."

10 "More worrisome for the high rate of
11 organ prolapse recurrence found with such short
12 follow-up of 3.6 months."

13 "Should be considered experimental until
14 the mesh erosion rate under" --

15 THE COURT: Okay. We heard that
16 testimony.

17 A. This is in the medical literature.

18 THE COURT: Doctor, stop. We
19 heard that testimony yesterday from you. It's --
20 I mean, it's out there and I understand that. But
21 we're never going to get through with this if you
22 don't answer one or two questions.

23 I understand that you think it was flawed
24 from the get-go.

25 THE WITNESS: I was just

1 addressing Ms. Jones' question about the medical
2 literature and what the discussion --

3 THE COURT: She just asked you if
4 they published their results.

5 THE WITNESS: And I was answering
6 that question, Your Honor.

7 THE COURT: She asks you what time
8 it is and you start telling her how to build a
9 watch.

10 THE WITNESS: I apologize, Your
11 Honor. I'm doing the best I can.

12 THE COURT: All right. Go ahead.

13 Q. (By Ms. Jones) I think the answer to my
14 question, Doctor, was that the French doctors,
15 Dr. Jacquetin and Dr. Cosson, published for the
16 world to see what they, the doctors doing this
17 study, found to be their results.

18 Am I correct?

19 A. Yes, you are.

20 Q. Now, when Prolift went on the market,
21 those doctors began to use the actual Prolift kit,
22 didn't they?

23 A. Yes, they did. And the tools --

24 Q. And in fact --

25 A. -- in the Prolift kit --

1 Q. Excuse me, Doctor.

2 A. -- had not previously been tested in
3 human beings. That was the first --

4 THE COURT: That was not the
5 question.

6 A. -- time --

7 THE COURT: That was not the
8 question.

9 The question was, did they start using
10 Prolift kits.

11 A. Yes.

12 Q. (By Ms. Jones) And when they did
13 those --

14 And when they started using Prolift, they
15 actually conducted studies on the Prolift and they
16 followed the women that were using Prolift, didn't
17 they?

18 A. Yes, they did.

19 Q. And they published those results, didn't
20 they?

21 A. Yes. With all the same --

22 Q. And Dr. Cosson --

23 A. -- issues we've already discussed.

24 Q. -- and Dr. Jacquetin used Prolift and
25 published those results, correct?

1 A. Yes, they did.

2 Q. Now, I want to show you -- or ask you
3 about an article that you talked about yesterday.
4 It's Plaintiff's Exhibit 108. It's the Collinet
5 article. Do you remember that?

6 A. Yes, I do. May I --

7 Q. And your --

8 A. Have a copy, please?

9 Q. Oh, surely. I thought surely you had
10 one, but I'll be glad to give you one.

11 A. Thank you.

12 Q. And what you told this jury yesterday was
13 about the exposure rates of 12%. Do you remember
14 that?

15 A. Yes, I do.

16 Q. And you also told this jury that what
17 these doctors had suggested were that experimental
18 studies and clinical trials seemed necessary to
19 reduce the level of exposure to less than 5%.
20 Correct?

21 A. Yes, that's right.

22 Q. And just so we're clear, so the jury
23 knows, this article was written, among others, by
24 Dr. Michel Cosson. Correct?

25 A. Yes.

1 Q. One of the principals of the TVM group,
2 correct?

3 A. Yes.

4 Q. What -- what I'd like to talk with you
5 about are some of the things about this article
6 that you did not tell the jury about. Okay?

7 A. By all means.

8 Q. So for example, the authors in this study
9 specifically said --

10 These are -- these are the authors that
11 you say are criticizing the mesh, correct?

12 A. What I said was that they were telling
13 Ethicon for years that --

14 Q. Excuse me.

15 A. -- a new mesh was needed.

16 Q. All right. There are --

17 A. I believe that's what I said.

18 Q. The jury can determine what you said. I
19 apologize. I don't mean to be short. I
20 apologize.

21 What, specifically, they said is that
22 recent years had been marked by research into the
23 mesh material most suited to this type of surgery.

24 A. I'm sorry. Could you tell me where
25 you're reading?

1 Q. I'm down at the bottom of the right --
2 right-hand column.

3 A. Okay.

4 Yes, I see. Thank you.

5 Q. And then it says, "It seems an
6 established fact that this should be a woven
7 monofilament polypropylene with large pores.
8 Since Prolene Gynecare fulfills these criteria, it
9 was used for all of the patients in this
10 particular study."

11 Correct?

12 A. That's what they wrote. That's not what
13 they were telling --

14 Q. That --

15 A. -- Ethicon.

16 Q. That's what they wrote here, is it not?

17 A. That is what they wrote.

18 Q. It is certainly not wrong for anybody to
19 try and seek an improvement on any product, is it?

20 A. It is appropriate when the women who are
21 being experimented on understand --

22 Q. Well --

23 A. -- that they're involved in an experiment
24 and give their permission to voluntarily
25 participate in an experiment. That is

1 appropriate.

2 Q. That was not my question, Doctor. My
3 question was very simple.

4 It is not wrong for anybody to try and
5 improve upon a product, is it?

6 A. It's not wrong as long as the
7 condition --

8 Q. And --

9 A. -- the conditions I mentioned are met.

10 Q. At the time that Dr. Cosson wrote this
11 paper, he specifically noted that there were ways
12 to limit the exposure rates, correct?

13 A. Again, can you -- could you point me out
14 to where you're referring, please?

15 Q. I'm just asking you just generally about
16 what Dr. Cosson, when he was talking about in this
17 paper, suggested that they ought to be looking for
18 ways to limit the exposure or erosion rate.

19 Correct?

20 A. Yes, that was one of their objectives, as
21 they mentioned.

22 Q. And in fact, what he noted was, under the
23 "Discussion" section --

24 And this paper actually is written in
25 2005, correct?

1 A. It was written in 2005, yes. It was
2 published in 2006.

3 Q. It says -- again, it says the same thing
4 again here about the ideal prosthetic material as
5 being the large mesh monofilament polypropylene
6 Prolene, correct?

7 A. That's what it says, and that's --

8 Q. And --

9 A. -- the kind of material that was --

10 Q. And --

11 A. -- resulting in such a high rate of
12 complications.

13 Q. And specifically what Dr. Cosson said
14 was, according to the authors this material helps
15 to limit the rejection rate --

16 And when they say rejection rate, they're
17 talking about the exposure or erosion rate,
18 correct?

19 A. Yes.

20 Q. -- to between 5 and 15%, correct?

21 A. Yes. And that's too high.

22 Q. And --

23 A. That's unacceptable and unsafe.

24 Q. Well, Doctor, I understand that's your
25 opinion and I think we all know that's your

1 opinion, but I want to ask you questions about
2 what these doctors said. Okay?

3 A. I -- I'm giving my opinion on what these
4 doctors say, yes.

5 Q. And -- and what these doctors
6 specifically said that you didn't tell this jury
7 yesterday was that in this study, they showed that
8 the level of exposure was less than 1% when the
9 uterus was preserved. Correct?

10 A. Yes. And that rate has never been
11 replicated and in --

12 Q. Doctor --

13 A. -- research done subsequently,
14 Dr. Hinoul, for example --

15 Q. Doctor --

16 A. -- questioned the veracity --

17 THE COURT: Just a minute, just a
18 minute, just a minute.

19 She just asked you about this. You
20 can -- when somebody asks you questions about
21 that, you can -- I'll let you pontificate all you
22 want to, but that's not what she asked you. She
23 asked you about this thing.

24 I know you know what's going on right up
25 till today, probably, but let's talk about then,

1 not now. Okay?

2 THE WITNESS: Yes, sir. Yes,
3 Your Honor.

4 THE COURT: All right.

5 Q. (By Ms. Jones) Did these doctors say
6 that in their study, they reduced the erosion rate
7 to 1% when the uterus was preserved? In other
8 words, when there wasn't a hysterectomy?

9 A. In this small group of women with very
10 short-term follow-up, yes.

11 Q. Now, we've talked about -- and you talked
12 about yesterday -- the recurrence rates in the TVM
13 study. Do you remember that?

14 A. Yes.

15 Q. And in fact, you put up on the board or
16 on the screen here what's been marked as
17 Plaintiff's Exhibit 1752. Do you still have that
18 up there?

19 A. I can look for it.

20 Q. I'll show you what I'm looking for.

21 A. If you have a copy, that might be faster.

22 Q. Well, I'm sorry, I didn't bring a copy of
23 what you used yesterday.

24 A. All right. 1752?

25 Q. 1752.

1 A. Yes.

2 Q. And if we could put that up, please, I
3 want to look at that first -- you see the --
4 right.

5 Now I want to talk about -- this is the
6 French TVM study that was done by the French
7 doctors that involved, as I recall, 90 patients.
8 Is that right?

9 A. Yes.

10 Q. And you show on here the Ethicon rate for
11 prolapse recurrence and one-year recurrence rate.
12 You see those?

13 A. Yes, I do.

14 Q. And I've got a couple of questions.
15 First, you show on there the Ethicon
16 six-month prolapse recurrence rate at 20.1%, and
17 then you show a one-year recurrence rate of 26.6%.

18 Do you see that?

19 A. Yes, I do.

20 Q. Both of those rates are significantly
21 below the 58% recurrence rate, for example, that
22 you reported in 2004. Correct?

23 A. They are. That's not relevant to this
24 study because it's higher than --

25 Q. Well --

1 A. -- their own defined endpoint.

2 Q. I'm going to get to that, so just let me
3 make sure because I want -- because I think it's
4 important for us, when we're talking about those
5 failure rates, to understand that those recurrence
6 rates are substantially below what was being
7 reported in the literature with other types of
8 surgery.

9 Correct?

10 A. Yes, that's true.

11 Q. Okay. Now, the fact of the matter is
12 that those rates that you put up there here are
13 not actually the rates that were reported in the
14 TVM study, are they?

15 A. I'm not sure I understand the question.

16 Q. Well, you've seen the final report that's
17 been marked as Plaintiff's Exhibit 49? The TVM
18 report?

19 Do you have this up here?

20 A. I don't have a copy, no.

21 Q. Well, let me hand you one.

22 MS. JONES: Counsel, I have one.
23 This is the previous -- it doesn't actually have
24 the plaintiff's exhibit on it. Thank you.

25 A. Thank you.

1 Q. (By Ms. Jones) And if we look at that
2 report, what I'd like to do is to look at the
3 conclusions section of it. And specifically,
4 Doctor --

5 I'm sorry, I may have handed you the
6 wrong -- the wrong study. Did I -- may I see the
7 one -- I just want to make sure I've given you the
8 right study.

9 All right. What I'd like you to do,
10 Doctor, is turn to the results and conclusions
11 that appear on what I have marked as the fourth
12 page there.

13 A. Okay.

14 Q. And if we bring up just the results and
15 conclusions, it specifically -- let's start with
16 the second -- let's start with the second
17 paragraph down here, okay?

18 The second paragraph talks about the
19 secondary effectiveness parameters showing a
20 failure rate at six months of 12.6%.

21 Do you see that?

22 A. Yes, I do.

23 Q. And then underneath that, it has the 90%
24 confidential interval. You see that?

25 A. Yes, I do.

1 Q. And the 90% confidence interval has two
2 numbers there. 7.3 and 20.1. Correct?

3 A. Yes.

4 Q. And if we look at those numbers --

5 And I think you testified yesterday that
6 the confidence intervals are what you look at to
7 determine the outer ranges of where the results
8 really fall. Correct?

9 A. No, that's not quite true.

10 Q. Well, am I not correct that what you
11 testified to -- and we can look at it and you can
12 explain it -- if you're looking at the confidence
13 interval, you put a confidence interval out there
14 and the confidence interval is a tool of
15 statisticians, correct?

16 A. Yes.

17 Q. And it's a tool of statisticians when
18 they show that some -- they show --

19 Actually, what the failure rate is as
20 here -- calculated up here was 12.6%, correct?

21 A. That is the average, uh-huh.

22 Q. The secondary effectiveness parameters
23 show a failure rate at six months of 12.6%,
24 correct?

25 A. Yes.

1 Q. And that's what's called the absolute
2 failure rate?

3 A. It's the average.

4 Q. And it's -- and it falls within the 7.3
5 and the 20.1, correct?

6 A. Yes.

7 Q. So what that's saying is --
8 What you're saying, as I understand it,
9 is that that's an average number that falls
10 between the two outside boundaries, if you will,
11 of the confidence interval. Correct?

12 A. That's substantially correct. It's, you
13 know --

14 Q. I'm not a statistician. That's just --

15 A. That's fine. I think --

16 Q. -- my interpretation.

17 A. -- we talked about it yesterday. I think
18 the jury understands.

19 Q. So -- and then if you go to the paragraph
20 above that, we're talking about the one-year data,
21 correct?

22 A. Yes.

23 Q. And it says the results show a failure
24 rate at 12 months of 18.4%, correct?

25 A. Yes.

1 Q. With a confidence interval there of 11.9
2 to 26.6, correct?

3 A. Yes.

4 Q. And again, what you would say is the
5 average failure rate is 18.4%, correct?

6 A. That's correct.

7 Q. That's what the authors of the study are
8 reporting, correct?

9 A. Yes.

10 Q. And the outside confidence interval,
11 which is the highest it might be under this study,
12 is 26.6%. Correct?

13 A. No, that's not quite right. This is a
14 90% confidence interval, so there -- that means
15 there's still 10% left.

16 But, yes, the upper bound of the 90%
17 confidence interval is 26.6%.

18 Q. And if we go back to Page 1750 -- or
19 Exhibit 1752, and what we were looking at, what
20 you showed the jury are only the upper limits of
21 the confidence level. Correct?

22 A. Right. That's because that's the primary
23 endpoint defined by the study protocol.

24 Q. That's what I want to get to, so --

25 A. Yeah.

1 Q. Because what you're show- --

2 The reason that that's there is that the
3 study and the protocol said, initially, if, in
4 fact, we look at the six-month deal, the Ethicon
5 rate exceeds 20%, it ought to be considered a
6 failure. Correct?

7 A. That if the upper bound of the 90%
8 confidence interval exceeds 20% at one year, then
9 that's a failure. Right.

10 Q. All right. And what this one did was
11 showed it at 20.1%, correct?

12 A. That's at six months. Correct.

13 Q. And if we turn to the second page and the
14 conclusion of what the author said, if we look in
15 "Conclusion" -- and we're looking at Page 49 --
16 it's specifically noted here that the study did
17 not meet the stringent predefined statistical
18 criteria.

19 And that's what we're talking about here,
20 correct?

21 A. That's correct.

22 Q. It then goes on to say that "The absolute
23 rate" -- "The absolute rate of 18.4%" --
24 Correct?

25 A. That's what it says, yes.

1 Q. -- "demonstrates the invaluable role of
2 TVM in treating patients with vaginal prolapse in
3 terms of reasonable success rates and a lower rate
4 of recurrence/reoperation compared to other
5 published studies."

6 Correct?

7 A. That's what it says. I disagree --

8 Q. And when --

9 A. -- with that conclusion.

10 Q. And when we're talking about -- just so
11 we're sure we're talking about other published
12 studies, we're talking about studies that had been
13 published, like yours and others, that show a high
14 recurrence rate of as much as 40%. Correct?

15 A. That's true.

16 Q. Now I'm going to switch gears a little
17 bit.

18 MS. JONES: Your Honor?

19 THE COURT: Yes.

20 MS. JONES: I know you said you
21 wanted to quit at 11:00 --

22 THE COURT: Yeah. Can we switch
23 gears here and we'll take a break?

24 MS. JONES: And I promise to get
25 organized and wrap it up.

1 THE COURT: That's all right.

2 Okay. I ran over a little bit here. I was going
3 to give you a break at 15 till and I just got so
4 mesmerized in statistics that I forgot about it.

5 MS. JONES: My fault.

6 THE COURT: Justice requires that
7 you not make up your mind about the case until
8 you've heard all of the evidence that's been seen
9 and heard and you must not discuss this case among
10 yourselves or with anyone else or comment on
11 anything you heard or learned in the trial until
12 the case is concluded and you retire to the jury
13 room for your deliberations.

14 Also, you must not remain in the presence
15 of anyone who is discussing the case when court is
16 not in session.

17 I've got about 12 minutes till. I'll
18 tell you what, let's be back here at five after.
19 That will give you a little over 15 minutes.
20 Okay?

21 See you at five after 11:00.

22 (The following proceedings were
23 held in the courtroom outside the presence of the
24 jury:)

25 THE COURT: All right. The jury's

1 out.

2 MR. SLATER: Thank you, Judge.

3 THE WITNESS: Thank you.

4 (Recess taken from 10:48 a.m. to 11:07 a.m.)

5 (The following proceedings were
6 held in the courtroom outside the presence of the
7 jury:)

8 THE COURT: Let's see. Are we
9 ready to bring the jury in? Okay. I don't know
10 whether we've still got one or two smokers out
11 or did they --

12 THE BAILIFF: Yeah. Let me go
13 make sure the smokers are here.

14 THE COURT: Yeah. I was going to
15 say I saw two gals walk this way and I figured
16 they were heading for a coffin nail.

17 He's going out to check on our two
18 smokers and then --

19 THE BAILIFF: You want me to fetch
20 them in? Are you ready?

21 THE COURT: I think he's going to
22 go see if they were there --

23 THE BAILIFF: Okay.

24 THE COURT: -- and then we'll get
25 the rest of them and, yeah, we're ready.

1 THE BAILIFF: They're both out
2 here, Judge.

3 THE COURT: They're both out
4 there?

5 Okay. So I guess we can bring them and
6 let them join them as we get the lineup here.
7 That usually means that one lady over there has to
8 walk all over everybody to get there because she's
9 out there, but that's okay.

10 (The following proceedings were
11 held in the courtroom in the presence of the
12 jury:)

13 THE COURT: Well, I believe we
14 have the panel in.

15 THE BAILIFF: All accounted for.

16 THE COURT: All right. You may be
17 seated, and we'll go back to where we were,
18 Doctor.

19 THE WITNESS: Thank you.

20 THE COURT: Yes, ma'am. Whenever
21 you're ready.

22 MS. JONES: May I proceed, Your
23 Honor?

24 THE COURT: Sure.

25 Q. (By Ms. Jones) Dr. Weber, I'm going to

1 try my best to move this along.

2 We talked about -- just a minute ago
3 about the fact that the Prolift came on the
4 market, the French doctors began using the
5 Prolift. Correct?

6 A. Yes.

7 Q. And we've published -- they have
8 published the results of their studies in using
9 the Prolift, have they not?

10 A. Yes, they have.

11 Q. And in fact, early on in 2006, there was
12 a study published by five of the French doctors,
13 the lead author being Dr. Fatton?

14 A. Do you have a copy of the article?

15 Q. I do have a copy of it. I just thought
16 maybe you would be familiar with it.

17 A. Oh, I am familiar with it, but I -- I
18 would like a copy, please.

19 Q. I'll hand you what's been marked as
20 Defense Exhibit 32016 --

21 A. Thank you.

22 Q. -- and ask you if that is a copy of a
23 study that was written by five of the French
24 doctors involved in the TVM group.

25 A. Yes.

1 Q. And this is the preliminary results from
2 the use of a new tension-free vaginal mesh Prolift
3 technique, of the case series, correct?

4 A. Yes.

5 Q. It notes that it's a multi-centric study.
6 That means it was performed by different doctors
7 in different medical centers, correct?

8 A. Yes, that's right.

9 Q. And in this particular study, the French
10 doctors were using not the TVM prototype Gynemesh
11 PS that they had used before, but were using the
12 actual Prolift. Correct?

13 A. Yes, that's right.

14 Q. And in this particular study, they found
15 an exposure rate of 4.7%, correct?

16 A. Yes. With three months of follow-up,
17 yes.

18 Q. And 4.7% is under the 5% that you
19 suggested Dr. Cosson suggested he needed earlier,
20 correct?

21 A. At very short-term follow-up.

22 We do know that the risk of mesh
23 complications is lifelong, so I would expect that
24 number to -- to go higher as time went on.

25 Q. But at least at this point in time it was

1 4.7%?

2 A. That is correct.

3 Q. And at this point in time, if you look at
4 the conclusions of the authors, they specifically
5 say that their findings suggest that transvaginal
6 use of mesh according to the Prolift technique is
7 a safe procedure. Correct?

8 A. I'm sorry. Could you let me know where
9 you're reading from?

10 Q. I'm at the conclusion.

11 A. Okay. Thank you.

12 Q. Am I right that what they -- they
13 concluded was, "Our findings suggest that the
14 transvaginal use of mesh according to the Prolift
15 technique is a safe procedure"? Correct?

16 A. That -- that is what it says.

17 Q. And then it says, "We need a longer
18 follow-up to confirm the effectiveness of the
19 procedure." That means whether or not it works.
20 Correct?

21 A. That's what it says, yes.

22 Q. And then it talks about prospective
23 evaluation of the functional outcome to support
24 widespread use of the technique and to recommend
25 it to young women with weakened tissues, correct?

1 A. That's what it says.

2 Q. And Ms. Budke obviously was not a young
3 woman with weakened tissues, was she?

4 A. She was not a young woman.

5 Q. So at least at this point in time, the
6 TVM group is actually publishing that they
7 considered this to be a safe procedure. Correct?

8 A. In my interpretation, yes, that this
9 refers to the immediate operative and
10 peri-operative results in terms of safety, since
11 this is three months of follow-up only.

12 Q. But their conclusion, as they published,
13 whether it's based upon that or their --

14 You know, by this time they also had had
15 the previous experience with the Gynemesh PS in
16 the prototype for the Prolift, correct?

17 A. Yes, that's correct.

18 Q. Now, I want to switch to a little bit
19 different subject, Doctor. I want to talk about
20 Stage 2 and Stage 3 prolapse. Okay?

21 A. Yes.

22 Q. And if we go back -- if we go back and we
23 look historically -- historically in the field of
24 urogynecology and gynecology, there were lots and
25 lots of procedures that had been done without

1 randomized controlled trials having been performed
2 on them, correct?

3 A. Yes, that's true.

4 Q. In fact, your 2001 study where you
5 reported on anterior colporrhaphy was one of the
6 first randomized studies that was done, correct?

7 A. Yes, that's true.

8 Q. And that is one of the first randomized
9 studies despite the fact that surgeons had been
10 doing these types of surgeries for 50 years, at
11 least. Correct?

12 A. Yes, that's true.

13 Q. And there's been some discussion in the
14 course of this case about -- and I think you
15 talked about yesterday the POP-Q measuring system
16 used by doctors?

17 A. Yes.

18 Q. And the POP-Q measuring system that kind
19 of measures where organs are --

20 And I think you said it was really
21 developed for research purposes. Correct?

22 A. Yes.

23 Q. And that was first developed for research
24 purposes and actually published, I think, in about
25 1996 or so by the American -- by the International

1 **Continenence Society?**

2 A. Yes, it was published in 1996, and that
3 was in the American Journal of Obstetrics and
4 Gynecology.

5 Q. And what was published at that point in
6 time was really, "This is the way we can consider
7 measuring them going forward," correct?

8 A. Yes.

9 Q. And you published that even as late as
10 2004. That was really still kind of in its
11 infancy, correct?

12 A. Yes, I believe that's fair to say.

13 Q. And it's a fair statement that doctors
14 were not all used to using that, correct?

15 A. Yes.

16 Q. Now, in terms of who the appropriate
17 women are for use of the Prolift, I want to talk
18 with you about that a little bit, okay?

19 A. Yes.

20 Q. In the protocols and in the TVM studies
21 done by the French, they -- the protocol called
22 for use of Stage 3 or 4 or more prolapse, correct?

23 A. Yes.

24 Q. There were, however, some protocol
25 variations and there were women who had only Stage

1 2 prolapse that were actually operated on by some
2 of the French doctors, correct?

3 A. Yes, that's true.

4 Q. And in fact, the protocol for the
5 Gynemesh PS study, the U.S. arm of the TVM study,
6 called specifically for Stage 2 and greater
7 prolapse, did it not?

8 A. Yes, that's correct.

9 Q. So just so we're clear, some of the
10 French doctors initially used it for Stage 2
11 prolapse. Correct?

12 A. Correct. As a protocol deviation, right.

13 Q. And as to the U.S. arm of that -- that
14 study, the protocol specifically provided for use
15 of the Gynemesh PS or the Prolift at Stage 2,
16 correct?

17 A. Symptomatic Stage 2 Prolifts, yes, that's
18 correct.

19 Q. And since that time, the -- well, let me
20 back up, just so it's clear.

21 And doctors, the U.S. doctors, on that
22 part of the study actually inserted or implanted
23 the Gynemesh PS, and subsequently Prolift, in
24 Stage 2 prolapse patients. Correct?

25 A. I'm not clear. Is that in the context of

1 the study or in their clinical practices?

2 Q. Let's just talk about the context of the
3 study.

4 A. Okay. So yes, symptomatic Stage 2
5 prolapse was --

6 Q. Stage 2 prolapse was included in that?

7 A. That's right.

8 Q. And subsequently, there have been
9 articles published by the French doctors where
10 they relate and show the use of the TVM mesh in
11 women who had Stage 2 prolapse?

12 A. Yes, I believe that's correct.

13 Q. And similarly, there have been
14 publications by the French doctors, including
15 Dr. Cosson, about -- that reference use of the
16 Prolift in women who had Stage 2. Correct?

17 A. Symptomatic Stage 2 prolapse, yes, that's
18 correct.

19 Q. In fact, it's not only symptomatic Stage
20 2 prolapse, there have been reports of some
21 patients that were used and published in the
22 medical literature where they had Stage 0 to 1
23 prolapse, correct?

24 A. Use of prolapse -- use of the Pro- -- I'm
25 sorry, I'm just trying to understand your

1 question.

2 Use of the Prolift procedure in patients
3 with Stage 0 prolapse? Is -- is that what you're
4 asking?

5 Q. I'm asking you if you're aware of reports
6 published in the medical journal -- medical
7 literature that show that women who had a Stage 0
8 to Stage 1 actually received a Prolift.

9 A. I'm not familiar. I -- I'd like you to
10 show me that if that's something that you're
11 holding in your hand.

12 Q. Are you familiar with the Landsheere
13 article?

14 A. Yes, I am.

15 Q. The Landsheere study? That's
16 Exhibit 31991.

17 A. Thank you.

18 Q. What I'd like you to do, Doctor, is
19 just -- all I really want to talk about about this
20 study at this stage is to talk about the -- the
21 table --

22 MR. OVERBY: Christy, do you have
23 an extra one?

24 MS. JONES: Oh, I'm sorry.

25 MR. OVERBY: No problem.

1 MS. JONES: You're just not in my
2 line of sight.

3 MR. OVERBY: Thank you.

4 Q. (By Ms. Jones) If you look at the table
5 on -- Table 1 --

6 A. Uh-huh.

7 Q. -- on Page 3199.3 [sic], you see that?

8 A. Yes, I do.

9 Q. And that is talking about patient and
10 surgical characteristics that received a Prolift?

11 A. Yes.

12 Q. And in there, they talk about 92 patients
13 having received a Prolift who have a POP-Q Stage 0
14 to 1?

15 A. Yes.

16 What I'd like to do is just see if they
17 included a description of the patients overall,
18 because what I suspect this means is that women
19 had more advanced prolapse in a different area of
20 the vagina.

21 And so as you know, there are three
22 different systems in the Prolift procedure -- an
23 anterior, a posterior, and a total -- so I'm just
24 wondering if those are not patients who had an
25 anterior Prolift procedure with a 0 to 1

1 cystocele.

2 Q. And it may very well be.

3 And certainly that would be appropriate
4 to use a Prolift in even a Stage 0 to Stage 1 if
5 you had another procedure that you're doing at the
6 same time?

7 A. No, I don't agree with that.

8 Q. Okay. It also shows that there were
9 Stage 2 procedures being treated with Pro- --
10 cystoceles being treated by Prolift?

11 A. Well, again, that's what you can't tell
12 from this article -- this table as to what -- what
13 type of the three systems were being put into
14 women with stages of this description.

15 Q. All right. Certainly if you look at the
16 table, it is clear that women with Stage 2
17 prolapse were receiving Prolift. Correct?

18 A. No, I don't agree with that.

19 Q. Well, Doctor, it says Stage 2 and it
20 identifies 70 patients, correct?

21 A. That doesn't mean that they were treated
22 with an anterior Prolift procedure, though,
23 because of their Stage 2 anterior vaginal
24 prolapse.

25 Q. And if you simply look --

1 All right. I understand what you're
2 saying, Doctor.

3 And what you've said is you just haven't
4 looked at the text of the paper to see if it
5 explains it more carefully?

6 A. I just don't recall that off the top of
7 my head. I have looked at the text of this paper.

8 Q. All right. There's no question, though,
9 in your mind, that Prolift has been used to treat
10 or to address women with Stage 2 prolapse, is
11 there?

12 A. Symptomatic Stage 2 prolapse.

13 Q. And certainly that was what was
14 contemplated and was included in the study, in the
15 French -- I mean, the U.S. study of Gynemesh PS,
16 correct?

17 A. Yes.

18 Q. And certainly you know that there's
19 published data that talks about the use of Prolift
20 in women who had Stage 2 prolapse?

21 A. Symptomatic Stage 2 prolapse, yes.

22 Q. And in fact, I think I may have asked you
23 this, Doctor, and I'm sorry if I'm repeating
24 myself, but in fact, the French doctors in the
25 Fatton study that we just talked about talked

1 about the use of Prolift in women who had Stage 2
2 prolapse, correct?

3 A. Symptomatic Stage 2 prolapse, yes.

4 Q. Now, I want to switch gears a little bit,
5 Doctor, because we've talked about recurrence
6 rates and failure rates, so I'm sure the jury is
7 tired of listening to them, and the fact of the
8 matter is that in this case, Ms. Budke didn't have
9 a recurrence of her prolapse, did she?

10 A. Mrs. Budke did not have a recurrence of
11 her prolapse. She was at very low risk of
12 recurrence in the first place, and since she only
13 lived for roughly a year and a quarter after her
14 Prolift procedure, she wouldn't have had time,
15 necessarily, to develop a recurrent prolapse.

16 Q. But in any event, the answer to my
17 question is: She did not have a recurrent
18 prolapse that's reported anywhere in the medical
19 literature -- records, is there?

20 A. No. You're right. She did not have a
21 recurrent prolapse.

22 Q. What Ms. Budke did have was an infection,
23 correct?

24 A. Yes.

25 Q. Now, you told us yesterday that

1 randomized controlled trials are important,
2 correct?

3 A. Yes.

4 Q. And as I recall your testimony, you told
5 us that they are important because only randomized
6 controlled trials can tell you whether there's a
7 causal relationship between two events. Correct?

8 A. In a research setting, yes, that's
9 correct.

10 Q. In the research setting.

11 And just so we --

12 We really haven't talked about this a
13 whole lot, so let me -- if we're talking about a
14 randomized controlled trial, so that the jury and
15 we all understand, what that means generally is
16 that if we take the case of Prolift, for example,
17 you have a group of women treated by doctors, and
18 half of them receive Prolift and half of them are
19 treated with traditional nonconventional [sic]
20 surgery or another type of product. Correct?

21 A. Traditional conventional surgery, I think
22 you may have meant to say, and that is one way to
23 set up a study, yes.

24 Q. All right. So -- and the purpose of it
25 is that --

1 You want the women to be as much alike as
2 you can, but the purpose is so that you can follow
3 the women over time and determine if there are any
4 differences between what happens with the group
5 who have Prolift versus what happens to the group
6 that has the more traditional surgery. Correct?

7 A. Yes.

8 Q. And so you look at that for different
9 reasons. One is to see whether or not it works
10 better, one surgery is more successful than the
11 other. Correct?

12 A. Yes, that is -- could be one of the
13 outcomes.

14 Q. And then you also can look at the
15 different complications that are reported over
16 time and compare those. Correct?

17 A. Yes, that's also commonly a very
18 important endpoint.

19 Q. Now, you told us yesterday, I believe,
20 that you had reviewed the medical and scientific
21 literature that related to Prolift?

22 A. Yes.

23 Q. And that would include the randomized
24 controlled trials, for example?

25 A. Yes.

1 Q. That would include those studies that
2 were done by others which were not necessarily
3 controlled trials but other types of studies?

4 A. Yes.

5 Q. And there are other types of studies that
6 are -- that can be done. One, just to follow the
7 women through and see what happens. Or two, to
8 retrospectively go back and look at the medical
9 records to see what's happened. Correct?

10 A. Yes. Those are two different study
11 designs.

12 Q. And those studies, regardless of what
13 type they are, generally include the complications
14 that are reported during the course of the study,
15 correct?

16 A. They may, certainly.

17 Q. That's certainly what you would expect
18 under normal circumstances is for those to include
19 a report of the complications, correct?

20 A. Yeah. I mean, of course it depends upon
21 the purpose of the study, but yes.

22 Q. And one of the things that you would
23 expect to be reported in the context of these
24 studies is the occurrence of infections associated
25 with Prolift. Correct?

1 A. Yes.

2 Q. And in fact, that medical literature has
3 looked at and evaluated infections associated with
4 Prolift, has it not?

5 A. Yes.

6 Q. And you would expect that to be so
7 because long before Prolift ever came on the
8 market, there were concerns about the ability of a
9 foreign material, any foreign material, to
10 potentiate infection that we talked about.
11 Correct?

12 A. Yes.

13 Q. And "potentiate infection," as you talked
14 about, means makes it more difficult to treat or
15 to manage?

16 A. That's one of its characteristics, yes.

17 Q. In fact, when we look at the medical
18 literature, the reported rates of infection
19 associated with Prolift are very low, aren't they?

20 A. In the range of 1%, yes.

21 Q. And in all fairness, some of the studies
22 have much lower rates and some studies have a
23 little bit higher rates, correct?

24 A. That is correct.

25 Q. But generally, it's 1% or lower of all

1 the people who had Prolift, correct?

2 A. I -- I think that's a fair assessment,
3 yes.

4 Q. Now, we've talked a little bit -- and I
5 don't want to go into it much because I'm going to
6 turn to something else, but we've talked about the
7 exposure rates and the erosion rates, correct?

8 A. Yes.

9 Q. And those are also rates that are
10 reported in the medical literature, correct?

11 A. Yes.

12 Q. And in all fairness, there's a pretty
13 wide range of the erosion rates or the infect- --
14 the exposure rates that have been reported,
15 correct?

16 A. Yes.

17 Q. And in fact, I think you've told me
18 beforehand -- and forgive me if I'm
19 misremembering, but I think you told me that
20 before 2000, before we ever got involved with
21 Gynemesh PS or whatever, there were reports of
22 erosion in the medical literature in terms of
23 people that had erosion when they had mesh put in
24 the body?

25 A. Yes.

1 Q. Including gynecological mesh --

2 A. Yes.

3 Q. -- being placed by gynecologists?

4 A. Yes.

5 Q. And that those rates appeared to be as
6 high as about 12% in some reports?

7 A. And higher, yes.

8 Q. Now, what I'd like to do now is to talk
9 about just one thing.

10 Am I correct that you testified that you
11 don't distinguish between exposure of mesh and
12 erosion of mesh?

13 A. I think the term "erosion" is a more
14 accurate representation of what's happened, and I
15 think it's more clear than to describe the
16 location of the erosion.

17 So to say "vaginal mesh erosion" or
18 "rectal mesh erosion" or "bladder mesh erosion"
19 gives anyone you're communicating with a very
20 clear idea of exactly what you're talking about.

21 Q. And I mean that's what you're describing
22 is in an ideal world, that's the way you'd like to
23 see things documented in the medical records or
24 the medical literature, for example?

25 A. Ideally, we would communicate with terms

1 that we understand.

2 Q. But the reality is that there have been a
3 number of different terms that have been used in
4 the medical literature, and even in the medical
5 records over time, correct?

6 A. Yes, I am sure that's true.

7 Q. And it's fair to say that sometimes
8 exposures have been reported as erosions, correct?

9 A. I'm not sure I understand the question.

10 Q. Okay. Well, let's -- what I'm really
11 just talking about is there are three different
12 words that have been used sometimes, and sometimes
13 interchangeably, correct?

14 A. Yes.

15 Q. And those words are "extrusion" --
16 A word we really haven't talked about
17 very much here, correct?

18 A. Correct.

19 Q. -- "erosion" and "exposure."

20 A. Yes.

21 Q. And my point is that doctors, even in the
22 medical literature, have used those terms in a --
23 sometimes somewhat of a confusing way. Correct?

24 A. Yes, I would agree with that.

25 Q. And there's not been a really good

1 definition of exactly what they were referring to
2 sometimes, correct?

3 A. Yes, I think that's true.

4 Q. And that also happens sometimes in
5 medical records, where doctors may use different
6 terms to describe the same -- the same event or
7 appearance in a body. Correct?

8 A. I think it's entirely likely that
9 different doctors use different terms. I would
10 expect that the same doctor would likely use the
11 same terms.

12 Q. Fair enough, fair enough.
13 And some doctors specifically use
14 "erosion" to refer to, for example, erosion into
15 another organ like the bladder. Correct?

16 A. That's correct.

17 Q. And some doctors use "exposure" to be
18 just when you can see or feel the mesh in the
19 vagina, for example, where there's no -- where you
20 don't know whether it just hasn't healed or not.
21 Correct?

22 A. I would agree that some doctors use
23 "exposure" when they're talking about a mesh
24 erosion in the vagina.

25 Q. Okay. And it's also fair to say that

1 even today, medical science doesn't understand
2 exactly how or what factors necessarily cause an
3 erosion. Correct?

4 A. Yes, that's correct.

5 Q. And there have been a lot of different --
6 there have been a lot of different things that
7 have been postulated about it, but right now what
8 we know is it's something that happens in the body
9 and we're not necessarily sure exactly what causes
10 it. Correct?

11 A. Yes, I think that's true.

12 Q. And there have been a lot of different
13 things --

14 I mean, you mentioned infection, but
15 among other things, they've talked about whether
16 or not -- you know, how it's placed or where it's
17 placed in the body. Correct?

18 A. Where the mesh is placed? Is that your
19 meaning?

20 Q. Right.

21 A. Yes, uh-huh.

22 Q. Or they've talked about whether or not a
23 woman, for example, has some medical problems that
24 keep her from appropriately healing?

25 A. Yes, that's been mentioned as one of the

1 possible factors.

2 Q. So one of the things we know is sometimes
3 if people aren't in good health for whatever
4 reason, their body may not heal as well as people
5 who are in good health. Correct?

6 A. Yes, I would agree with that.

7 Q. And the same thing has been happening --
8 this is not true here, but for example it's the
9 type of thing where people say that smokers, for
10 example, may not heal as well as people that don't
11 smoke. Correct?

12 A. Yes, I believe that's been reported.

13 Q. And that -- all of those things apply to
14 the pelvic area and the vagina, the place where
15 the Prolift is placed in a woman, correct?

16 A. Yes.

17 Q. Now, those are all things that were
18 generally discussed in the medical literature
19 before 2008, weren't they?

20 A. Yes. I -- I think doctors and scientists
21 have been trying to understand fully the cause of
22 mesh erosions.

23 Q. And it's fair to say that doctors and
24 surgeons that you expect to be using Prolift are
25 generally experienced pelvic floor surgeons,

1 correct?

2 A. I don't have the knowledge, you know,
3 since, when Prolift was available on the market
4 for widespread use, there weren't controls in
5 place to assign or sift out who could use the
6 Prolift and who couldn't.

7 Q. And in all fairness, hospitals decide
8 that, don't they?

9 A. In what way?

10 Q. Well, we're getting a little bit far
11 afield, but generally doctors are credentialed to
12 perform certain surgeries in their hospitals,
13 correct?

14 A. That is true. I -- I'm --

15 Q. And -- and generally, just generally,
16 doctors have to show to the hospital board, or
17 whoever the appropriate person is, that they're
18 qualified to do or have experience doing certain
19 surgeries, correct?

20 A. That's true in general.

21 Q. I don't want to get too far afield on
22 that, but in many hospitals, for example, there
23 are only a limited number of doctors who are
24 approved to do certain types of surgeries.

25 Correct?

1 A. Yes, that's correct.

2 Q. All right. And that may vary by
3 hospital.

4 A. I'm sorry. Was that a question?

5 Q. I said, and that may vary by hospital.
6 Yes.

7 A. Yes, it may.

8 Q. Now, in terms of the Prolift, what I'd
9 like to do is we've talked a little bit about
10 what -- what information was out there.

11 What I'd like to do is to talk with you a
12 little bit because I don't think we've really
13 talked with the jury about what specific
14 information doctors -- Ethicon gave doctors with
15 respect to things like infection and erosion that
16 we've talked about, and I'm going to hand you
17 what's been premarked as Defense Exhibit two
18 thousand- -- 20001, which is the IFU.

19 MS. JONES: And I confess,
20 Counsel, I don't know if you introduced that.

21 MR. SLATER: I believe -- I
22 believe we've used the IFU multiple times. I
23 think I used it -- in fact, Dr. Simpson, I think I
24 presented it to her.

25 MS. JONES: I just don't have the

1 right number there, but we'll clear it up, Your
2 Honor.

3 MR. SLATER: It's not a problem.

4 THE COURT: All right. Y'all can
5 work that out. You both kind of know what this
6 is.

7 MS. JONES: I know.

8 MR. SLATER: That's right.

9 THE COURT: All right. That's
10 good enough. You can educate the jury and me
11 about it later, okay?

12 Q. (By Ms. Jones) We'll clear it up but for
13 our record, we're going to refer to Prolift [sic]
14 2000.1, Doctor, and, Doctor, what I've handed to
15 you is the instructions for use as it relates to
16 Prolift.

17 MR. SLATER: I think it's 1005.

18 THE COURT: 1005.

19 MS. GUNN: Yeah. We don't need
20 suspense. We have it on the floor here.

21 THE COURT: So instead of 20001,
22 it's 1005?

23 MR. SLATER: Yes, Your Honor.

24 THE COURT: Got it.

25 MR. SLATER: That will be the

1 first and last time I can find anything for
2 anyone.

3 THE COURT: Well, good enough.

4 MS. JONES: At least me, I'm sure.

5 MR. SLATER: That's it.

6 Q. (By Ms. Jones) All right. Doctor, what
7 I'd like you to do is to turn, if you would, to
8 the sixth page.

9 And this instructions for use -- so that
10 we can orient the jury, the instruction for use is
11 a lengthy document that has a lot of information
12 in it, including information about how the
13 procedure is performed and so forth. Correct?

14 A. Yes.

15 Q. You were asked some questions about this
16 yesterday, but I want to talk with you just about
17 the contraindications, warnings, and adverse
18 reactions. Okay?

19 A. Yes.

20 Q. And if we look specifically at the
21 warnings, I'd just like to talk about a couple of
22 these.

23 It says, "Number 2. Acceptable surgical
24 practices should be followed in the presence of
25 infected or contaminated wounds." Do you see

1 **that?**

2 A. Yes, I do.

3 **Q. Now, in fairness, that's not what we're**
4 **talking about here, are we? In Mrs. Budke's case?**

5 A. We're certainly talking about an infected
6 wound. An infected Prolift mesh.

7 **Q. But -- well, but my point is that what**
8 **this is telling the doctor is that you don't want**
9 **generally to -- that if you're concerned about**
10 **there being an infection in place at the time that**
11 **you perform the surgery, you want to take special**
12 **care that surgeons normally take. Correct?**

13 A. I'm not sure I understand the question.
14 Are you asking me how I interpret this
15 sentence or -- or exactly what?

16 **Q. Let me just ask this.**

17 A. Okay.

18 **Q. I think I confused it by going someplace**
19 **probably not particularly important here, but what**
20 **this refers to is if, in fact, a surgeon is**
21 **operating where there is an infection in the area,**
22 **the surgeon needs to follow acceptable practices.**
23 **Correct?**

24 A. Okay. So you're talking about a
25 preexisting infection.

1 Q. Well, doesn't that -- isn't that what
2 that's referring to?

3 A. That's one possible type of infection
4 it's referring to, yes.

5 Q. All right. As -- when a surgeon -- I
6 think I can clear this up in a second.

7 Just before that, it says, "Users should
8 be familiar with surgical procedures and
9 techniques involving pelvic floor repair and
10 nonabsorbable meshes before employing the
11 Gynemesh" -- "the Gynecare Prolift pelvic floor
12 repair system."

13 You see that?

14 A. Yes, that's what it says. Ethicon had no
15 way of actually ensuring that's what took place.

16 Q. Exactly.

17 Surgeons -- you, as a surgeon, wouldn't
18 do a pelvic floor repair surgery if you didn't
19 think you were familiar with it, would you?

20 A. I would not. You're right.

21 Q. And you would expect that what that's
22 saying is that doctors that used the Prolift ought
23 to be familiar with those procedures. Correct?

24 A. That's -- that is what it says, yes.

25 Q. Now, if we come down to "Adverse

1 Reactions" and we highlight the first bullet point
2 there, it talks about potential adverse reactions,
3 and so we're all on the same wavelength, those can
4 be complications following the surgery or
5 associated with the product, correct?

6 A. Yes.

7 Q. "Potential adverse reactions are those
8 typically associated with surgically implantable
9 materials."

10 You see that?

11 A. Yes, I see that.

12 Q. And then it goes on to say "including
13 infection potentiation, inflammation, adhesion
14 formation, fistula formation, erosion, extrusion,
15 and scarring that results in implant contraction."

16 You see that?

17 A. Yes, I do.

18 Q. Now, that's the information that was
19 provided by Ethicon to doctors in the kit that
20 contains the Prolift, correct?

21 A. Yes, that's correct.

22 Q. And that information, when we're talking
23 about surgically implantable materials, those
24 potential complications are complications that are
25 associated with virtually every implantable

1 material. Correct?

2 A. Those are some of them. That's not all
3 of them.

4 Q. Well, fair enough.

5 Erosion, extrusion, and scarring that
6 results in implant contraction would apply to all
7 meshes. Correct?

8 A. Yes.

9 Q. Now, it also says down here, "Sterility.
10 The Gynecare Prolift pelvic floor repair systems
11 are sterilized by ethylene oxide. Do not
12 resterilize. Do not reuse. Do not use if package
13 is opened or damaged. Discard all opened unused
14 devices." Correct?

15 A. Yes.

16 Q. And that's a precaution that's taken to
17 ensure that the product is not contaminated at the
18 time it's implanted in the patient. Correct?

19 A. That's taken to make sure the product is
20 not contaminated by the time it's turned out on
21 the surgical table.

22 By the time it's implanted in the
23 patient, it's contaminated by virtue of having
24 passed through the vagina, which cannot be
25 sterilized.

1 Q. Well, but hold on with me one second.

2 We'll get there.

3 As a practical matter, you know from your
4 review of the documents that all Prolifts are
5 sterilized when they leave the manufacturing
6 facility, correct?

7 A. They are sterilized. I've seen issue
8 reports of contaminated kits where hair was
9 found -- sterile hair, no doubt, but hair found
10 within the kit.

11 Q. Certainly no indication that any hair was
12 found in Mrs. Budke's kit, was there?

13 A. No, not that I know of.

14 Q. You've seen Ms. Budke's batch records?

15 A. I'm sorry?

16 Q. You've seen the batch records on --

17 A. Oh, the batch records. Yes, yes.

18 Q. And the batch records for Mrs. Budke's --
19 the Prolift that she received showed that it went
20 through the appropriate sterilization techniques?

21 A. Yes. As I'm sure did the kits that ended
22 up with hair in them.

23 Q. And -- and -- I'm sorry?

24 A. As -- I'm sure the kits that ended in
25 hair with them went through the standard

1 sterilization process and --

2 Q. You know, Mrs. -- Dr. Weber, let's --
3 let's talk about Mrs. Budke for a second.

4 A. Certainly.

5 Q. Her batch records, the batch records on
6 the Prolift that she did, showed that it was
7 appropriately sterilized when it left the
8 manufacturing facility. Correct?

9 A. Yes, that's correct.

10 Q. And you have no reason to suggest to this
11 jury that Ms. Budke's Prolift was in any way
12 contaminated when it got --

13 A. No, I didn't mean to imply that. No, not
14 at all. Not -- no, no. That wasn't my meaning at
15 all.

16 Q. Thank you.

17 And the purpose -- one of the purposes of
18 ensuring that all of the kits are sterilized is to
19 avoid the possibility of infection that comes from
20 simply having bacteria on the device when you
21 implant it into the body?

22 A. The bacteria are on the device after
23 passing through the vagina.

24 It comes out of the box in a sterile
25 condition, yes.

1 Q. Comes out of the box in a sterile
2 condition, and it's fair to say, Doctor, that
3 gynecologists have been operating on the vagina
4 for years and years and years. Correct?

5 A. That is correct.

6 Q. And the vagina is and has normal
7 bacterial flora in it, correct?

8 A. Yes, it does.

9 Q. And one of the things that doctors are
10 taught in their residency, or whatever, as
11 gynecologists is how to safely operate in that
12 field. Correct?

13 A. Yes.

14 Q. And how to avoid contamination by the
15 bacterial flora. Correct?

16 A. The contamination cannot be avoided.

17 Q. Well, I'll tell you what, we'll let some
18 other doctors talk about that.

19 The fact is that if -- if there were
20 significant problems with surgical contamination,
21 you would have expected to see much higher rates
22 of infection in the randomized controlled studies,
23 wouldn't you?

24 A. No, I don't think that's true.

25 Q. Okay. The -- the IFU was not the only

1 information that was given to doctors about
2 Prolift and the complications associated with it,
3 was it?

4 A. That's correct.

5 Q. And in fact, Ethicon provided to
6 physicians a document called a surgeon's resource
7 monograph, did it not?

8 A. Yes.

9 Q. And that surgeon's resource monograph,
10 I'll hand you what's been marked as Defense
11 Exhibit 24240.

12 A. Thank you.

13 MR. SLATER: I'm sorry, Your
14 Honor. Could we just step up real quick?

15 THE COURT: Sure.

16 MR. SLATER: I think, Kent, I've
17 got to ask you and David a question, too.

18 (Counsel approached the bench and
19 the following proceedings were held outside the
20 hearing of the jury:)

21 MR. SLATER: I just want to
22 clarify one thing because I read Dr. Simpson's
23 deposition and I don't -- I don't think she saw
24 this, or if she did, I'm not sure, but she's going
25 to be talking about a document she never saw and I

1 don't think she ever relied on this or used it, so
2 I just don't want to introduce -- you know, a
3 document as an important warning document that the
4 doctor didn't even see, and I don't think she did.

5 MR. OVERBY: She wasn't asked
6 about that at the depo.

7 MR. HYDE: She has seen one
8 version of it at some point.

9 MR. SLATER: One version.

10 MR. HYDE: I don't know if there's
11 different generations or not.

12 MR. SLATER: Do we know if this is
13 the right one or --

14 MR. BALL: This is the only one
15 that predates the surgery.

16 MR. SLATER: Okay. I just wanted
17 to --

18 THE COURT: Okay. I take it
19 that's a "yes."

20 MR. SLATER: I have a lot of
21 redirect on it. I just wanted to make sure we
22 didn't waste time. I'll be going for a while on
23 it.

24 THE COURT: Okay.

25 (The proceedings returned to open

1 court.)

2 Q. (By Ms. Jones) Doctor, you've seen this
3 surgeon's resource monograph?

4 A. Yes, I have.

5 Q. And this is a monograph that was made
6 available to doctors by Ethicon?

7 A. Yes.

8 Q. And in addition, it was used in certain
9 professional education courses? Or do you know
10 that?

11 A. No, I don't know that.

12 Q. All right. What I'd like to do is see if
13 we can walk through this with the jury so that we
14 can look at some of the information that was shown
15 to the jury about -- to the doctors and told to
16 the doctors about infection and exposure. Okay?

17 A. Certainly.

18 Q. And if we look at --
19 What I'd like to do is to turn to the
20 table of contents which is on Page 2.

21 A. Okay.

22 Q. And if we look at Page 2 --
23 Actually, let's -- so that we're clear,
24 this document was actually authored by doctors and
25 urogynecologists?

1 A. Yes, that's true.

2 Q. And if we look at then the table of
3 contents, I want to talk specifically with you
4 about what was discussed with doctors about the
5 complications, infection, and then mesh
6 complications: erosion, exposure, and
7 extrusion. Okay?

8 A. Yes.

9 Q. And let's turn to Page 4, the next page,
10 and at the time this was written, in the
11 "Introduction," at this time there had been over
12 35,000 procedures done with respect to Prolift,
13 correct?

14 A. Yes, that's what it says.

15 Q. And it points out that there are seven
16 known case series in progress, correct?

17 A. Yes.

18 Q. And a case series is a study underway
19 following the women that have had these surgeries,
20 correct?

21 A. Yes.

22 Q. And then it goes on to point out what we
23 just said, that the comments and opinions
24 contained within this document represent the
25 experiences of the 10 authors as well as over 200

1 participating international prolapse surgeons.

2 Correct?

3 A. Yes.

4 Q. In fact, it goes on to say that the way
5 they collected this information is that this is a
6 summary of the collective experience of the most
7 experienced Gynecare Prolift system users who were
8 invited to attend one of five user forums
9 throughout the world. Correct?

10 A. Yes. So this is anecdotal experience.

11 Q. It's anecdotal experience based upon that
12 information, but it's information that was
13 collected from over 200 doctors, correct?

14 A. Right. Anecdotal, yes.

15 Q. And if we look down to the "Preparation"
16 portion down here -- I'm going to skip around a
17 little bit before I get to the -- one of the
18 things that they report under "Preparation" is
19 "Infection rates have been exceptionally low and
20 only typical antibiotic prophylaxis is required."

21 Now, what that's referring to is in many
22 surgeons -- or many surgeries, a doctor will,
23 before they ever start the surgery, or at the
24 time, give a dose of antibiotics just to ward off
25 infections. Correct?

1 A. Yes.

2 Q. But it does say there that infection
3 rates have been exceptionally low, and that would
4 be consistent with what you've told us that had
5 been reported in the literature. Correct?

6 A. Yes.

7 Q. And then if we turn to Page 8, please,
8 there's a section on infection.

9 A. Yes.

10 Q. And when we're talking about the section
11 on infection, it says, "There have been very few
12 known cases of infection related to the Gynecare
13 Prolift system. In this rare event, the mesh will
14 often need to be extracted, although it is
15 assisted by lack of ingrowth surrounding infected
16 tissue. There is data to support the conservative
17 management of infections when in the presence of
18 monofilament polypropylene" -- "in the presence of
19 monofilament polypropylene."

20 Then it goes on to talk about a
21 peri-rectal abscess, correct?

22 A. That's what it says, yes.

23 Q. So let's talk about this just a little
24 bit because when it says "There have been very few
25 known cases of infection related to Prolift,"

1 that's correct, and that's consistent with what's
2 been reported in the studies, correct?

3 A. Yes.

4 Q. It then goes on to say when it is, you
5 may have to extract the mesh. Correct?

6 A. That's what it says.

7 Q. And that's something that's consistent
8 with what medical doctors know may happen when
9 you've got a foreign body present in the body in
10 the presence of infection, correct?

11 A. Yes. And the principle is to remove all
12 of the infected material, and we know in the
13 Prolift system that's not possible.

14 Q. Well, just stick with me a minute.
15 You've been doing pretty well. Stick with me a
16 second.

17 As a practical matter, that's what that's
18 relating to is you want to extract the mesh
19 because of the possibility that it may potentiate
20 infection, make it difficult to treat. Correct?

21 A. That's correct.

22 Q. And then it goes on to say, "There is
23 literature to support the conservative management
24 of infections when in the presence of monofilament
25 polypropylene." You see that?

1 A. That's what it says.

2 Q. And that's what it says because, in fact,
3 there are studies out there that suggest that in
4 the presence of a monofilament polypropylene mesh,
5 you may not need to remove the mesh. You may be
6 able to treat it without removal. Correct?

7 A. And there are studies, including by the
8 French doctors, who say that the mesh needs to be
9 extracted completely.

10 So there are different practices
11 recommended in the medical literature.

12 Q. Fair enough.

13 My question is -- and the one I want to
14 make sure you answer is -- that there are studies
15 out there and there are suggestions out there by
16 people who are expert in treating infectious
17 diseases that suggest that in some cases you can
18 treat infection with polypropylene present without
19 having to remove it. Correct?

20 A. Yes, I think that's correct.

21 Q. Now, in this case, no question but what
22 Dr. Simpson thought that the correct thing to do
23 was to extract the mesh, correct? In Ms. Budke's
24 case.

25 A. Yes, she did --

1 Q. That's what Ms. -- that's what
2 Dr. Simpson elected to do when Ms. Budke presented
3 with an infection. Correct?

4 A. Yes. She removed a portion of the mesh.

5 Q. Now, in addition to the discussion of
6 infection, there is also a discussion immediately
7 below that on the mesh complications erosion,
8 exposure, and extrusion. Correct?

9 A. Yes.

10 Q. And we've got that word up there again,
11 "extrusion." What -- what this document says and
12 what Ethicon, when it gave to doctors,
13 specifically noted was that there's no uniformity
14 of terms used for mesh complications.

15 You see that?

16 A. Yes, I do.

17 Q. That's the same thing you and I were
18 talking about earlier; that sometimes people use
19 "erosion," "exposure," and "extrusion" in
20 different ways?

21 A. Yes.

22 Q. And it goes on to say --
23 I'm going to leave out "extrusion"
24 because that's not -- I don't think "extrusion"
25 appears anywhere in Ms. Budke's medical records,

1 does it?

2 A. I don't think so.

3 Q. It says, "'Erosion' and 'extrusion' are
4 the most appropriate terms, and although they are,
5 in fact, similar in definition, it may be wise to
6 reserve the term 'erosion' for the more serious
7 visceral erosion. This would help avoid
8 confusion."

9 Do you see that?

10 A. Yes, I do see that.

11 Q. Now, what that's referring to is a
12 suggestion that, for example, an exposure may
13 simply be a failure to heal or the mesh may simply
14 be seen, for example, through a suture line, as
15 opposed to erosion actually going through and
16 eroding to the bladder, as we discussed. Correct?

17 A. Actually, I don't see any of those terms
18 there as far as I don't see "suture line," I don't
19 see "healing." I -- I don't see what you're
20 discussing there.

21 Q. I understand it's not there. I was
22 trying to get it -- explain what we were talking
23 about, the difference between exposure and
24 erosion --

25 A. Oh, I didn't understand.

1 Q. -- and if you're not familiar with that,
2 that's --

3 A. Okay.

4 Q. -- we can move on.

5 A. Okay.

6 Q. Visceral erosion occurs when the mesh
7 erodes through an organ like the bladder, correct?

8 A. Yes, that's -- that's correct.

9 Q. And it contrasts that, in the second
10 paragraph, with the known occurrence of simple
11 vaginal mesh exposure. You see that?

12 A. Yes.

13 Q. Mesh exposure, which obviously some
14 people would refer to as erosion -- I'm not trying
15 to confuse things -- occurs in 3 to 17% of cases.
16 You see that?

17 A. That's what it says, but the upper range
18 is actually quite a bit higher.

19 Q. Well, I think you told us earlier -- and
20 forgive me if I'm wrong, but I thought you told us
21 earlier this morning that there had been a range
22 of reports in the studies of erosion that range
23 from as low as 3% to as high as 20%.

24 A. Or higher, yes. "And higher," I should
25 say.

1 Q. And it's fair to say, Doctor, that if you
2 look at all of the medical literature that's out
3 there and the studies that are reported, that
4 there are some factors associated with the
5 reporting rate in different studies. Correct?

6 A. Yes.

7 Q. And in some cases, as the surgeons become
8 more familiar with the surgery, the rate of
9 exposure goes down?

10 A. People have reported that, yes.

11 Q. And in some cases, there have been
12 reports of the use of different types of mesh and
13 their different exposure rates?

14 A. Yes, that's correct.

15 Q. And that when you change from one mesh to
16 another mesh, the exposure rate goes down?

17 A. It changes. It may not go down; it may
18 go up.

19 Q. They change. Fine.

20 You know you've seen reports of where
21 it's gone down?

22 A. I'm not -- are you talking about a direct
23 comparison?

24 Q. I'm talking about reports in the medical
25 literature where a doctor moves from one type of

1 mesh to another type of mesh and sees a dramatic
2 improvement.

3 A. Do you -- are you referring to a specific
4 article?

5 Q. Well, let me ask you this: I think that
6 you mentioned this yesterday. You know that when
7 the French doctors started studying this, they
8 didn't initially start studying the development of
9 this product with Gynemesh PS, did they?

10 A. That's correct.

11 Q. In fact, they started with other meshes,
12 including a Prolene mesh that's different.
13 Correct?

14 A. Yes.

15 Q. And you know that the French doctors said
16 their exposure rate went from 17% to about 2.7%,
17 as I recall, when they did that?

18 A. When they were also experimenting with
19 the procedure itself.

20 So it's not purely the mesh. There were
21 other factors that were going on during that time
22 of experimentation.

23 Q. Fair enough.

24 The point is, the exposure rate dropped
25 from 17% to less than 3%, didn't it?

1 A. I believe those figures --

2 Q. At one point.

3 A. -- are relatively accurate, yes.

4 Q. If we go on and we look at the other
5 information that was furnished to doctors, they go
6 on to say, "Experience and avoiding hysterectomy,
7 when possible, will reduce the rate to 1 to 6%."

8 Do you see that?

9 A. I do see that.

10 Q. In fact, that's consistent with what was
11 reported by Dr. Cosson, correct?

12 A. Yes.

13 Q. And it also seems -- says that "Exposure
14 may spontaneously resolve if seen in the first six
15 weeks but seems unlikely to resolve if seen after
16 that time," correct?

17 A. That's what it says, yes.

18 Q. And you know that to be true as reported
19 in the medical literature?

20 A. It may occur, yes.

21 Q. It also says, "They are often
22 asymptomatic and require no treatment, in that
23 case." You see that?

24 A. I do see that.

25 Q. And asymptomatic requiring no treatment

1 means that it's not causing the woman any
2 problems. Correct?

3 A. At that moment, it's not. That's
4 correct.

5 Q. Well, at any moment if it's asymptomatic,
6 it's not causing her any problems, is it?

7 A. There's a risk for future, but at that
8 moment, correct.

9 Q. Well, there's a risk that I may be hurt
10 falling down the stairs, right? But today, I'm
11 standing here right now and I'm fine, right?

12 A. I appreciate your analogy --

13 Q. I apologize, I apologize.

14 A. -- but the mesh as a lifelong implant --

15 Q. I'm sorry, doctor.

16 A. -- carries the permanent risk of
17 complications.

18 Q. Doctor, I apologize for my analogy.

19 The fact of the matter is that when
20 someone is asymptomatic, what that means is
21 they're not having any problems. Correct?

22 A. At that moment, that's correct.

23 Q. All right. And at that moment, they
24 don't require any treatment. Correct?

25 A. I don't agree with that.

1 Q. All right. Fine.

2 It then goes on to say -- and I think
3 this is what you were just trying to say --
4 "Experience has demonstrated that it is not
5 uncommon for the initially asymptomatic exposures
6 to become symptomatic over time." Correct?

7 A. That's what it says.

8 Q. That's exactly the point you're trying to
9 say, correct?

10 A. That's -- yes, that's true.

11 Q. So if you just stick me, I'll get there.
12 It goes on to say that, "The symptoms may
13 be mild, ranging from spotting or leukorrhea to
14 dyspareunia and/or vaginal pain," correct?

15 A. That's what it says, yes.

16 Q. And it goes on to say, "Intervention is
17 usually quite minimal with local excision under
18 sedation. It can be performed in the office,
19 especially with small defects and if there is some
20 capability of sedation." Correct?

21 A. That's what it says.

22 Q. Well, the fact of the matter is that it
23 had been -- we've seen in the medical literature
24 that when doctors are reporting on the studies,
25 what doctors have reported in the medical and

1 **scientific literature is consistent with that**
2 **statement, is it not?**

3 A. No, I don't agree.

4 Q. You don't agree that there are reports by
5 **doctors that specifically say, "We've looked at**
6 **exposures and a certain percentage of those**
7 **exposures are asymptomatic"?**

8 A. That's the key point, "a certain
9 percentage" --

10 Q. All right.

11 A. -- "that are asymptomatic," and --
12 Go on.

13 Q. So a certain percentage are asymptomatic
14 **and require -- well, doctors have chosen not to**
15 **treat them, whether you agree with it or not.**
16 **Correct?**

17 A. That's correct.

18 Q. And they have reported that they required
19 **no treatment, correct?**

20 A. At that moment, that's correct.

21 Q. And they have also reported that in many
22 **of those cases, you can just go in and do a small**
23 **excision in the office to treat it. Correct?**

24 A. I don't agree with that. I don't --

25 Q. You don't agree that that's what's been

1 **reported?**

2 A. I don't agree with "many." This is the
3 key --

4 Q. If you --

5 A. That's a key concept.

6 Q. If -- well, let's -- just stick with me,
7 Doctor.

8 If we go back and we look at the studies,
9 many of those studies report erosion rates,
10 correct?

11 A. Yes.

12 Q. And many of those reports include women
13 who they say have exposure or erosion but no
14 symptoms. Correct?

15 A. In some cases.

16 Q. And many of those doctors have chosen not
17 to treat those women or to give them vaginal cream
18 or vaginal estrogen, correct?

19 A. Which is a treatment, yes.

20 Q. Well, it is a treatment and I apologize
21 if I've misstated something.

22 Other doctors have said sometimes if that
23 doesn't do it, you go in and do a little clipping
24 in-the-office procedure, correct?

25 A. Yes. I imagine that's intensely

1 uncomfortable.

2 Q. That's what doctors have reported. Am I
3 correct?

4 A. Yes.

5 Q. Now, if we look at the second -- the next
6 page of this document, it says, "The true etiology
7 of mesh exposure is unclear and may vary."

8 You see that?

9 A. Yes, I do.

10 Q. That's exactly what we were just talking
11 about earlier, that there are many potential
12 theoretical bases for what causes erosion.
13 Correct?

14 A. Yes.

15 Q. And medical science simply hasn't
16 determined the cause of that today. Correct?

17 A. That's right.

18 Q. And as we sit here today, you're not
19 aware -- well, strike that.

20 It goes on to say, in the final
21 paragraph, that, "The best prevention is strict
22 adherence to the surgical technique guidelines
23 with full-thickness incision, good tissue
24 handling, no vaginal trimming, tension-free wound
25 closure and keeping the mesh flat and

1 **tension-free. The largest number of vaginal**
2 **exposures is in the anterior incision line and**
3 **they are generally less than 2 centimeters in**
4 **largest dimension."**

5 **You see that?**

6 A. That's what it says.

7 That's the problem with anecdotal reports
8 like this in terms of "the largest number,"
9 "generally less."

10 As we already know, women who have
11 complications move on to a different doctor, they
12 may move on to a tertiary referral center. These
13 doctors may not have experience with the women who
14 have the most severe complications because they go
15 away from their practices.

16 So this is what they report, but this is
17 by no means a comprehensive summary of the kinds
18 of complications, mesh complications, that women
19 experience.

20 **Q. Doctor, I want to go back to the**
21 **beginning.**

22 **This document was written by experienced**
23 **pelvic floor surgeons who were using Prolift,**
24 **correct?**

25 A. Who were all Ethicon consultants.

1 Q. Well, you would expect Ethicon to have
2 gotten consultants to -- someone to write this,
3 wouldn't you?

4 A. Every time I've looked more deeply into
5 what Ethicon consultants have written and produced
6 in terms of research, that has raised grave
7 concerns about their scientific honesty.

8 Q. Doctor, we've just been through three and
9 four and five paragraphs of a lengthy document
10 where Ethicon was furnishing information about
11 infection to doctors, correct?

12 A. Yes. And that's the concern that the --

13 Q. And --

14 A. -- information is inaccurate and
15 misleading.

16 Q. That's your opinion, Doctor.

17 A. It's not just my opinion.

18 Q. There's nothing I can do to change that
19 today, so let's just talk about the fact that as a
20 practical matter, the information that was
21 presented --

22 A. Excuse me.

23 Q. This information was presented to
24 doctors, correct?

25 A. Yes.

1 Q. Made available to doctors to help them --
2 or to educate them about what had been reported in
3 the literature, correct?

4 A. No. This is based on surgeons'
5 experience, anecdotal experience, and it doesn't
6 help them if the information is misleading and
7 inaccurate.

8 Q. All right, Doctor.

9 MS. JONES: With all due respect,
10 Your Honor, I move to strike the comment and ask
11 that it be disregarded.

12 MR. SLATER: Your Honor, I think
13 that was responsive, with all due respect.

14 THE COURT: Well, asked and
15 answered. I'm -- I'll allow that one time. I
16 don't want to get into that web again, okay?

17 By the way, while we got a lull here, do
18 you know what -- Ms. Jones, what might be a
19 convenient breaking point? Because we're now on
20 to 12:30, but I'll -- go ahead. I don't want to
21 break a thought process but I'm just --

22 MS. JONES: I'm sorry, Your Honor.
23 I --

24 THE COURT: That's all right.

25 MS. JONES: I was being coached by

1 my colleagues and I didn't --

2 THE COURT: I'm sorry.

3 MS. JONES: -- I didn't hear what
4 you said.

5 THE COURT: Oh, okay. Well, what
6 I said was I've been giving them a dinner break
7 around 12:30. That's not written in stone. It
8 could be a quarter of 1:00, I guess. We'll clean
9 the restaurants out more. But just kind of a
10 preliminary warning that somewhere here we're
11 going to take a noon hour.

12 Q. (By Ms. Jones) Doctor, with the
13 admonition of the court, I'm going to ask this one
14 question.

15 MR. BALL: Can we talk for just a
16 second?

17 MS. JONES: I apologize. If
18 you'll indulge me one second.

19 THE COURT: What's that? Okay.
20 You may confer.

21 (There was a discussion off the record.)

22 Q. (By Ms. Jones) Doctor, in talking about
23 this particular document, if we go back to the
24 first page here, the very introduction, in this
25 introduction it's talking about 35,000 procedures

1 in seven known case centers with interim --
2 studies -- series with interim results available,
3 correct?

4 A. Remind me again where you are.

5 Q. I'm in the introduction.

6 A. Oh, I beg your pardon. I thought you
7 were in the foreword.

8 Okay. Yes.

9 Q. And specifically, this refers to the
10 collective experiences of 200 participating
11 international prolapse surgeons, correct?

12 A. That's what it says.

13 Q. And what it's referring to is that these
14 are the comments and this is the information that
15 was collected and statements made by over 200
16 doctors worldwide that were actually using the
17 Prolift. Correct?

18 A. This is anecdotal information that was
19 not systematically collected.

20 Q. Doctor -- Doctor, my question is very
21 simple.

22 It's important to have information from
23 doctors that are actually doing the procedure, is
24 it not?

25 A. It's important to have accurate and fair

1 and balanced information.

2 Q. And -- and, Doctor, the best place to get
3 information, the very best place to get
4 information, about a product is from doctors who
5 actually are treating patients with the product.
6 Correct?

7 A. If it's accurate and fair and balanced.

8 Q. Well, Doctor, are you telling me that you
9 think that there are 200 or over 200 people out
10 there that are giving inaccurate information?

11 You're not saying that, are you?

12 A. They --

13 Q. You're not saying that, are you?

14 A. Anecdotal information is --

15 Q. Doctor, please answer my question.

16 A. Excuse me. I'm trying to answer your
17 question.

18 Q. I'm asking you to answer my question.

19 Very simply, are you saying to this jury
20 that there are 200 -- over 200 recognized pelvic
21 floor surgeons doing this surgery that are all
22 dishonest? Is that what you're saying?

23 A. No. What I'm saying --

24 Q. Thank you.

25 A. -- is that anecdotal information is, by

1 its nature, incomplete, and what we know has been
2 well-established in the literature is that
3 patients with complications seek care elsewhere
4 and that leaves the original surgeon with a
5 misperception of what happens to patients,
6 especially on the worst-case scenario end of the
7 spectrum.

8 Q. Doctor --

9 A. That's what I'm saying.

10 Q. Doctor, you would also agree with me that
11 one of the best places to get information about
12 women and how they are -- how they are -- how
13 they -- how well -- strike that.

14 You would agree with me that one of the
15 best places to go to determine how women responded
16 and what the actual complications are are the
17 studies that have been done?

18 Do you agree with me on that?

19 A. No. The studies that have been done,
20 particularly by Ethicon investigators, have such
21 serious flaws that those results are not reliable.

22 Q. So, Doctor, what you're saying to this
23 jury -- let's just be perfectly clear --

24 A. Uh-huh.

25 Q. -- is that the results --

1 You told this jury yesterday that you
2 were not aware of any transvaginal mesh product
3 that had more published data on the safety and
4 efficacy of the product than Prolift.

5 Do you remember that?

6 A. More is not better --

7 Q. Well --

8 A. -- and every time I've chance to
9 review --

10 Q. Doctor --

11 A. -- the raw data of studies paid for by
12 Ethicon --

13 Q. Doctor --

14 A. -- the results --

15 MS. JONES: Your Honor --

16 A. -- have been vastly --

17 THE COURT: All right.

18 A. -- different than --

19 THE COURT: Okay.

20 A. -- what's been published.

21 THE COURT: Enough. Enough.

22 Let's take a lunch break. Okay?

23 Justice requires you not make up your
24 mind about the case until all the evidence has
25 been seen and heard. You must not discuss this

1 case among yourselves or with anyone else or
2 comment on anything you hear or learn in this
3 trial until the case is concluded and you retire
4 to the jury room for your deliberations.

5 Also, you must not remain in the presence
6 of anyone who is discussing the case when the
7 court is not in session.

8 That ends the reading.

9 Have a nice noon hour. It's -- be back
10 here at 12:30, 1:30 -- 25 till 2:00. When the big
11 hand is on 7 here.

12 JUROR: Okay.

13 (The following proceedings were
14 held in the courtroom outside the presence of the
15 jury:)

16 THE COURT: The jury's out.

17 Okay. Well, we'll take an hour break.
18 Do I need to be back at any special time? Do we
19 have anything that's --

20 MS. JONES: Your Honor, I've
21 got --

22 THE COURT: -- pressing before we
23 start again?

24 MS. JONES: I have -- I may have a
25 two-minute thing. No more than two minutes.

1 THE COURT: All right. Okay.

2 MS. JONES: But I may not.

3 THE COURT: You mean --

4 MR. BALL: We may need like five
5 minutes to make a final record before they come
6 back in.

7 THE COURT: Yeah. Okay.

8 Well, all right. Let's see. I'll be
9 back in when the big hand is on the 5. That's 10
10 minutes before it goes to the 7.

11 MR. SLATER: You said you guys
12 have something to talk about with Your Honor?

13 MS. JONES: Huh?

14 MR. SLATER: You said you guys
15 have something to talk about before --

16 MS. JONES: I may.

17 MR. SLATER: Yeah, we may have
18 something to raise too, so it may be good to give
19 us a few minutes.

20 THE COURT: All right. I'll get
21 back here when the hand's on 5 and they're going
22 to go back on here when it gets on 7 and I'd like
23 to have them in here when it gets on 8. Okay?

24 MR. SLATER: Thanks a lot, Judge.

25 THE COURT: About as simple as I

1 can make it.

2 MR. HYDE: I like it.

3 MR. SLATER: Reminds me of a
4 Fisher-Price clock.

5 THE COURT: Thank you. Huh?

6 MR. SLATER: Remember the
7 Fisher-Price clocks --

8 THE COURT: Yeah.

9 MR. SLATER: -- and they'd have a
10 little song that would play.

11 THE COURT: Yeah. In fact, the
12 one I used to rely on was a Mickey Mouse clock,
13 you know. When the little gloved hand's on 3 and
14 the big one's is on 5 till, it's about time for
15 school to get out. All right.

16 (Recess taken from 12:33 p.m. to 1:29 p.m.)

17 (The following proceedings were
18 held in the courtroom outside the presence of the
19 jury:)

20 THE COURT: Hello. Everybody got
21 here about the time the hand's on the big 5, I
22 guess, or whatever. The big hand was on the 5.
23 I'll get it right in a minute.

24 MR. SLATER: I think, Ms. Jones,
25 you had an issue? Christy did.

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1 MS. JONES: Hold on one second.

2 MR. BALL: Okay. So Adam?

3 MR. SLATER: Yes.

4 MR. BALL: I'm going to go ahead.

5 We've got a couple things.

6 MR. SLATER: Okay.

7 MR. BALL: Following up on our
8 discussion before court started this morning, we
9 would like to ask two questions.

10 First question: "Dr. Weber, are you
11 primarily employed by Mr. Slater?"

12 We'd like a ruling that that doesn't open
13 the door to other lawsuits.

14 MR. SLATER: Well, she's not
15 employed by me.

16 MR. BALL: That's what she said in
17 her deposition.

18 MR. SLATER: She's not a W-2
19 employee. She's gets a 1099. She's a consultant
20 who works with me.

21 MR. BALL: That's what she said --

22 MR. SLATER: So I'd have to
23 clarify that.

24 MR. BALL: Okay.

25 THE COURT: "Are you a full-time

1 consultant?"

2 MR. BALL: "Are you a full-time
3 consultant for Mr." --

4 THE COURT: Someplace she said she
5 wasn't doctoring anymore and --

6 MR. SLATER: Yeah. I mean, I
7 don't know -- whatever. He can ask whatever he
8 wants. We'll clean it up. I mean --

9 MR. BALL: No. So I want -- so
10 that would be --

11 THE COURT: No, I will not treat
12 that as opening the door if you don't go beyond
13 that.

14 MR. BALL: Okay. Second question
15 is -- and this is -- this is directly related to
16 what we talked about before. We would like a
17 ruling that if we ask the question "How much have
18 you been paid by Mr. Slater," then she -- and
19 she'll give an answer, then that we ask for a
20 ruling that that not open the door to other
21 lawsuits.

22 MR. SLATER: I think in the
23 interest of time, Your Honor, I think you've
24 already heard extensive argument. I think
25 Your Honor gave us a clear ruling. I really would

1 prefer not to reargue an issue that we spent a lot
2 of time on this morning. I think we all
3 understood what you said.

4 MR. BALL: I'm asking for a
5 specific ruling to that question. I'm not --

6 THE COURT: Well, here -- here --

7 MR. BALL: I'm not trying to
8 reargue it.

9 THE COURT: -- here's the whole
10 thing. She has said that she charged a thousand
11 dollars an hour to testify, right? Am I right on
12 that?

13 MR. SLATER: For deposition --
14 yeah, for trial testimony.

15 MR. BALL: Yeah.

16 THE COURT: She charged \$350 an
17 hour --

18 MR. SLATER: To look at stuff.

19 THE COURT: -- to look at stuff.
20 I'll take that job if you got an extra one open.
21 I can -- I'm an avid reader. But -- yeah, right.

22 But anyway, I know surely that would
23 satisfy the fact that she's done pretty well with
24 you, and -- rather than just setting a figure.
25 Because once you set that figure, then the

1 question becomes, "Well, what did" --

2 MR. ANDERSON: "What did you do?"

3 THE COURT: -- "what did you do,
4 because you surely -- if they're paying you that
5 kind of money for what you're doing here, you'll
6 have all kinds of applicants."

7 MR. SLATER: That's what I
8 normally pay people for --

9 THE COURT: You can ask her again,
10 "Now, Doctor, what did you say your rate was?"

11 MR. BALL: No. We've already done
12 that.

13 THE COURT: All right.

14 MR. BALL: So I just want to make
15 sure that we have a clear ruling on the record.

16 So the ruling would be that if --

17 THE COURT: That you can ask --

18 MR. BALL: -- that if we ask how
19 much she's been paid by Mr. Slater total, then you
20 would view that as opening the door for them to
21 ask some questions about other lawsuits.

22 THE COURT: Well, I think probably
23 so. I mean, I think that's what they're going to
24 say and then we're going through all of this
25 again.

1 I think that if you set out -- if you
2 want to reiterate that -- I mean, I'm not telling
3 you to do it, but if you're going to, stick with
4 what she's said. That is, "You've been charging a
5 thousand dollars" --

6 MR. ANDERSON: "At trial."

7 THE COURT: Yeah.

8 -- "for trial work and 350 for research,
9 and your -- basically your job at this point in
10 your life is consulting for Mr. Slater?"

11 MR. BALL: Okay. Then --

12 MR. SLATER: And she'll answer it
13 however she does and we'll move on.

14 THE COURT: Yeah.

15 MR. BALL: And then the -- so then
16 I would make an offer of proof, then --

17 THE COURT: Yes. That if you
18 were --

19 MR. BALL: -- an offer of proof
20 that if we were allowed to ask the question about
21 how much she has been paid by Mr. Slater, that she
22 would say that at the time of the deposition it
23 was 800 and some-odd thousand dollars last summer
24 and it's more since that time and it's approaching
25 a million dollars.

1 THE COURT: Whatever you know. I
2 have no idea.

3 MR. BALL: That would be our offer
4 of proof. Is that acceptable?

5 THE COURT: Yeah. As an offer of
6 proof, I -- that's fine.

7 MR. SLATER: Yeah. I think the
8 testimony would probably be close to that. It
9 would probably be it's over \$800,000, and I
10 haven't added up the final number but I would
11 agree it's over \$800,000 and I think that's
12 what --

13 THE COURT: Well, I think that --
14 let me tell you this: I don't think our juries
15 here are particularly stupid. They seem to be
16 figuring out things pretty well in cases I've been
17 handling lately. And I think they're going to
18 figure out somehow that if you're -- if you're the
19 consultant -- if she's your consultant, that she's
20 getting paid for it. And, you know --

21 MR. BALL: So --

22 THE COURT: But we'll make the --
23 let's go ahead.

24 MR. BALL: -- our offer of proof
25 is denied?

1 THE COURT: No.

2 MR. BALL: We can do it with her.

3 MR. SLATER: You don't deny an
4 offer of proof. You just make it for the record.

5 THE COURT: No, no. It's a
6 record.

7 MR. SLATER: You're just making a
8 record.

9 MR. BALL: So --

10 MR. SLATER: We have -- I'm sorry.

11 THE COURT: Here's what my ruling
12 will be, and then you can make your offer of
13 proof.

14 My ruling is that I'm going to let you
15 ask what she does and if she -- if her primary
16 professional thing at this point is a consultant
17 for his -- his firm or for Mr. Slater. I don't
18 even know -- if I had a test, I don't even know
19 where you live. I know it's in New Jersey, but,
20 you know, that's a fairly big state.

21 And if you want to start it with that or
22 end it with that, you can ask her, "Now, you've
23 told us in this -- in this trial that you're
24 getting a thousand dollars an hour to testify and
25 \$350 an hour to do research and the like."

1 MR. BALL: Okay. Thank you, Your
2 Honor.

3 THE COURT: All right.

4 MR. SLATER: Thanks. We have an
5 issue we wanted to put in front of Your Honor now
6 because Dr. Weber is here and it's something that
7 I think would be a fair thing to ask her.

8 Before the trial, Your Honor provided a
9 ruling regarding the fact that Ethicon has stopped
10 selling the Prolift as of 2012, and Your Honor
11 said, "Look, I'm not going to have the plaintiffs
12 put it in in the first instance, but if the
13 defendants put the issue in, open the door to it,
14 then it could come in."

15 We believe the door has been opened
16 because of this. Two things.

17 The reason the Prolift was withdrawn was
18 because -- and we can do this, by the way -- I
19 want to preface it -- without ever mentioning the
20 FDA.

21 THE COURT: All right. Yeah, I
22 don't want that.

23 MR. SLATER: No. I'm going to
24 tell you what happened but I'm telling you right
25 now it can be done without saying "FDA."

1 THE COURT: Okay. That's a
2 compound felony so I don't want to get into that.

3 MR. SLATER: In early 2012,
4 January 3rd, the FDA said "You've got to do this
5 study," a high-level clinical study, the type
6 Dr. Weber is saying was never done, "and you need
7 to do that so you can prove this is safe and
8 effective. It needs to be a three-year study and
9 then we're going to make some decisions on, you
10 know, whether or not we're going to let these be
11 sold anymore."

12 The net-net of the story was, the deal
13 that was made was Ethicon went to the FDA and
14 said, "Look, we're pulling the product off the
15 market so we don't want to do the study."

16 And the FDA said, "Fine. If you -- if
17 you pull it off the market, you don't have to do
18 these studies, but if you ever want to try to come
19 back with it, you're going to have to do the
20 studies to get on."

21 Now, that's number one.

22 They have -- Ms. Jones has stated to the
23 jury in opening and with Dr. Weber that the
24 Prolift is the most studied medical device for
25 vaginal repair of prolapse that has ever existed.

1 And I'm paraphrasing, but that's the
2 message.

3 She's told the jury about all the
4 studies. She put up a list of studies in opening
5 and, you know, I think there was about 12 studies
6 on the graph in the PowerPoint. And she's
7 repeatedly asked Dr. Weber all morning about the
8 fact that Ethicon has heavily studied the product
9 and proven it's safe, and was reading, in fact,
10 from articles. For example, the 2007 article by
11 the TVM group saying it's safe.

12 And then she referenced the fact that
13 they had published more studies, the three- and
14 five-year results were studied, and they're saying
15 it's safe, and that goes into like 2011, those
16 articles. 2010 and 2011. I think maybe even
17 2012. And has made it clear to the jury that
18 their position is, there's plenty of studies
19 proving it's safe and effective.

20 The fact is, when Ethicon was told "You
21 need to do the high-level study and have it
22 watched over and have no slips in it and no
23 openings," Ethicon made the choice to withdraw the
24 product rather than do the study.

25 They have an explanation for it. They

1 say it was a business decision, they weren't
2 making a lot of money on it. That's fine. That's
3 the kind of thing that gets presented.

4 How -- and the other reason why I think
5 the door has been opened is they have talked about
6 the wide acceptance of the Prolift. They've told
7 the jury it was put in 35,000 women. And they
8 have repeatedly suggested that doctors love this
9 thing and there's a lot of doctors who use it all
10 the time. Ms. Jones has spoken in present tense
11 multiple times.

12 So you put those things together and all
13 we want to do is play the --

14 First of all, Dr. Weber should be able to
15 say that because she's in a box and she knows she
16 can't say that they pulled it off the market on
17 that date. She's not saying that explicitly. But
18 she should be able to say that on redirect.

19 The second thing is -- and we don't have
20 to argue the details of it now, but we have a
21 short deposition clip of the regulatory affairs
22 guy at Ethicon who handled this who testifies to
23 the story of it, and I think it's about a
24 25-minute video that we have, so we'd want to be
25 able to play that to the jury to show them what

1 happened, or, you know, maybe we don't even have
2 to do that. Maybe we can just do it where
3 Dr. Weber says it and we stop there.

4 You know what? That's fine. I'd be
5 happy to just put it out.

6 And all she would say is when the subject
7 came up that they needed to do this type of study,
8 not saying who brought it up or anything, that
9 they made a decision not to sell the Prolift
10 anymore, rather than do that study, and it's
11 not -- no longer sold, and that's it.

12 And I think that that's a fair way to
13 handle the fact that the jury's been given the
14 type of evidence that clearly needs to now be
15 answered.

16 THE COURT: Okay. Now, let me ask
17 one question here --

18 MR. BALL: Can I respond?

19 THE COURT: Yeah, I'll let you.

20 Tell me about what is this M+ or +M?

21 MR. SLATER: Okay. As you've
22 seen, there was this hernia mesh that was
23 partially absorbable.

24 THE COURT: Uh-huh.

25 MR. SLATER: And going back to

1 2004, the scientists at Ethicon were looking at
2 that and saying, "You know what? We think this
3 could be safer because there will be less material
4 left in the body after it absorbs."

5 What it is, it's the same type of mesh
6 here, partially, and then something called
7 Monocryl, which absorbs into the body. Absorbable
8 sutures. And it turns out to have about, I think,
9 45% less material when it absorbs like over 80
10 days. So it's leaving less mesh in the body. So
11 they figured maybe it would be softer, maybe you'd
12 have less inflammation, maybe it wouldn't cause as
13 many erosions, not as many problems. And as
14 you've seen, they consistently within the company
15 thought it was going to be a safer product.

16 They did that study on it and then
17 eventually they got clearance and sold the Prolift
18 with the Monocryl, with the UltraPro. They
19 started selling that in early '09, and that's what
20 Dr. Simpson adopted and stopped using the Prolift
21 and went to the Prolift+M at that time.

22 And the Prolift+M was on the market, and
23 then when they -- when they actually pulled the
24 Prolift off, they pulled the Prolift+M at the same
25 time. Pulled them both off the market. And

1 that's what the Prolift+M is, and we've been very
2 careful in not mentioning it.

3 THE COURT: I know that because --
4 yeah.

5 MR. SLATER: You know, we're not
6 going to go over your -- even though there's been
7 some questions that got close --

8 THE COURT: Yeah.

9 MR. SLATER: -- we're not
10 mentioning the Prolift+M and we've been careful
11 about that.

12 So that's also off the market.

13 MR. BALL: We need to respond.

14 THE COURT: Yeah. I'm going to
15 listen.

16 Okay. Ms. Jones?

17 MS. JONES: Thank you, Your Honor.

18 First, Your Honor, this is a matter
19 that's been already ruled upon. Your Honor
20 excluded the evidence of a discontinuance on the
21 ground that it was more prejudicial than
22 probative.

23 I'll remind you that every other court
24 that's ever considered it has done exactly the
25 same thing. The evidence has never come in.

1 With respect to some claim that we've
2 opened the door, all of the studies that were
3 referred to specifically and that we've pulled up
4 were early studies talking about the TVM study and
5 whatever.

6 We did talk about, and Dr. Weber did
7 acknowledge the existence of, the other studies
8 that had looked at it and what their infection
9 rates were and so forth, but that doesn't in any
10 way, shape, or form mislead the jury. Those are
11 what those study results were, period.

12 And there's been no suggestion, Your
13 Honor -- I mean, when we talk about 35,000 women
14 that use the Prolift, what we showed up there was
15 a 2007 document shortly after it went on the
16 market. That has nothing to do with suggesting
17 that it's still on the market today. That's what
18 was done in 2007 before Ms. Budke ever got --

19 THE COURT: Well, I think it --
20 yeah. I mean, and that's --

21 MS. JONES: -- implanted.

22 MR. BALL: The simple matter is,
23 Your Honor, we cannot get a fair trial here if
24 they're allowed to come up here and say that we
25 withdrew this from the market. We are not able to

1 get a fair trial if they're able to say four
2 years --

3 THE COURT: I thought I ruled that
4 we wouldn't talk about that.

5 MR. BALL: You did. They're
6 trying to now say -- they're trying to now say --

7 THE COURT: That you opened the
8 door and that --

9 MR. BALL: -- by discussing the
10 fact that it is un- --

11 We also have to defend the claim that the
12 product is defective. The way you defend that
13 claim is to -- and, well, they also have a claim
14 of negligence, okay?

15 They also have a claim of punitive
16 damages.

17 THE COURT: Yes. And I've been --

18 MR. BALL: The way that you defend
19 those claims is by proving the product has been
20 tested.

21 We -- if they're saying that we -- that
22 by us saying that the product has been extensively
23 tested opens the door to us not being able to sell
24 it anymore, we wouldn't be able to defend any of
25 the claims because their claims are all based on

1 testing and things.

2 So this is -- this is just an attempt at
3 an end-run around your ruling.

4 THE COURT: Okay. Well, let me --
5 let me rule.

6 MR. BALL: Thank you.

7 THE COURT: Well, go ahead.

8 MR. BERGMANIS: What I was going
9 to say is you don't have to tell them that there's
10 how many thousands of these? 32,000 or --

11 MR. SLATER: Well, actually their
12 opening slide said 120,000 women, and they're
13 talking in the present tense and how safe it is
14 and the studies prove it's safe, and the language
15 of Your Honor's ruling, just so you know it, it
16 said "unless the defendant chooses to put the
17 subject into evidence."

18 They've put the subject in evidence by
19 saying the studies prove it's safe, but they
20 declined to do a study that would have proven it
21 wasn't and, instead, stopped selling it.

22 MR. BALL: That's ridiculous. We
23 have not -- we have not put the withdrawal of this
24 product in the market [sic]. All we have done is
25 defended ourself against their claim that we were

1 negligent, and that's it.

2 THE COURT: Well, I'm going to let
3 them argue all their claims but we're not going to
4 talk about the fact that -- how it got stopped.

5 MR. BALL: Thank you.

6 THE COURT: All right.

7 MR. SLATER: We could tell you if
8 we think they kicked the door too hard, right?

9 THE COURT: Yeah. Yeah. I
10 don't -- I hate to hear crying and gnashing of
11 teeth.

12 So anyway, let's -- I think you're going
13 to get fine here with that, and that stays fairly
14 consistent with what the other judges have done.

15 THE BAILIFF: Ready for him to
16 round up the jurors?

17 THE COURT: Yeah. Yeah.

18 Mr. Bergmanis?

19 MR. BERGMANIS: Yes, sir.

20 THE COURT: Let me talk to you
21 just one second.

22 MR. BERGMANIS: Are we off the
23 record, Judge?

24 THE COURT: Yeah, I'm off the
25 record on this.

1 (There was a discussion off the record.)

2 THE BAILIFF: All rise.

3 (The following proceedings were
4 held in the courtroom in the presence of the
5 jury:)

6 THE COURT: Good morning. Or good
7 afternoon. Yeah, it is afternoon.

8 JUROR: It is afternoon.

9 THE COURT: It really is.

10 THE BAILIFF: Found every one of
11 them.

12 THE COURT: Yes, you did, it looks
13 to me like. If I got enough fingers, you got
14 everybody here.

15 THE BAILIFF: If that doesn't
16 bother the Court.

17 THE COURT: No, I don't know --
18 huh-uh. That doesn't bother me a bit.

19 THE BAILIFF: The jury panel was
20 complaining about the glare.

21 THE COURT: Oh, well, we don't
22 want to put their eyes out. I'll tell you, the
23 sun's bad enough but I don't have much control
24 over it. That's kind of like ordering your dog
25 around.

1 Okay. We got everybody here. You may be
2 seated, and with the exception of the doctor,
3 because she stands, and she's going to go to the
4 witness stand.

5 And I'll remind you that you're still
6 under the same oath you were a day ago.

7 THE WITNESS: Yes.

8 MS. JONES: Dr. Weber, thank you.
9 I have no more questions for you today.

10 THE WITNESS: Thank you.

11 MR. BALL: I tender the witness,
12 Your Honor.

13 THE COURT: Yes.

14 MR. OVERBY: Going to be me, Your
15 Honor.

16 THE COURT: Well, that's just fine
17 with me, Mr. Overby.

18 MR. OVERBY: I figured.

19 I won't be long, Doctor.

20 THE COURT: Your partner will keep
21 copious notes. I can see that because he's got
22 his pen and pencil in hand. Okay.

23 CROSS-EXAMINATION

24 QUESTIONS BY MR. OVERBY:

25 **Q. Here's where I want to start on I think**

1 some things that we'll agree on. Maybe -- maybe
2 when we're said and done, we'll agree on
3 everything here, you and me here today.

4 But we -- I've met you at least once
5 before in your deposition in this case. True?

6 A. Yes.

7 Q. And you understand that there are -- that
8 there may be more than two claims but there are
9 two parts to this case. There are claims that are
10 pending relating to the plaintiff's claim against
11 Ethicon or Johnson & Johnson.

12 You're aware of that?

13 A. Yes.

14 Q. And that there are -- there is a claim
15 pending with respect to Dr. Simpson, whom I
16 represent.

17 You understand that?

18 A. Yes.

19 Q. And that claim has to do with whether or
20 not she met the appropriate standard of care.
21 Right?

22 A. I understand that, yes.

23 Q. And we talked about this back at your
24 deposition. I just want to make sure that
25 everybody else is clear.

1 Your testimony here is not related to
2 that claim against Dr. Simpson. True?

3 A. Yes, that's correct.

4 Q. Okay. And you've talked about peer
5 review. There's been a lot of discussion about
6 peer-reviewed journals. It sounds to me like --

7 First of all, I think you've made this
8 point several times. Just because it's peer
9 reviewed doesn't mean it's right.

10 That's a point you've made, right?

11 A. Yes.

12 Q. You've had peer-reviewed stuff of your
13 own published. I assume you probably think it's
14 all correctly done, though. Right?

15 A. To the best of my ability, yes.

16 Q. You sure hope so.

17 The doctors out there like Dr. Simpson
18 don't necessarily know, without digging into the
19 data that may or may not be available, those kinds
20 of details as to, in other words, whether or not
21 the data provided was accurate or not.

22 Fair enough?

23 A. That's correct.

24 Q. There has been some discussion about
25 literature that's been published at different

1 points in time, and some of that literature, at
2 least -- one of them I kept track of simply
3 because I know there's a summary.

4 What was this (indicating)? Exhibit --
5 it's Plaintiff's Exhibit 139 or 139A. It's
6 actually not in English, right?

7 A. The entire article is not in English --

8 Q. Right.

9 A. -- you're correct.

10 Q. There's a summary in English?

11 A. The abstract is in English, yes.

12 Q. So things get published in the literature
13 all over the world, correct?

14 A. Yes.

15 Q. And doctors like Dr. Simpson can read
16 this. To the extent that they have opportunity
17 and time and dig deep enough for whatever it is,
18 they can see what the literature says. That's one
19 thing doctors do do, can -- can do and do do,
20 right?

21 A. Yes.

22 Q. And I don't want to get into a discussion
23 with you, if I can avoid it, about staging and the
24 appropriateness or inappropriateness of using
25 products in staging other than this: You are

1 **aware that doctors and patients have chose**
2 **together, through the years -- forget about**
3 **mesh -- okay? -- completely -- to address**
4 **surgically Stage 2 and sometimes Stage 1 prolapse.**
5 **Fair?**

6 A. Symptomatic.

7 Q. Right. I understand.

8 But that's -- that's happened, right?

9 A. Yes.

10 Q. In fact, if we look at a couple -- if I
11 **come over here, this will make it easier and**
12 **quicker, I think.**

13 These are just a few that I pulled that
14 **were discussed with you.**

15 514, that's one you're an author on,
16 **right?**

17 A. Yes.

18 Q. Remind me what the gist of this one was.

19 **This is an '04 article that talks about the**
20 **recurrence rate after repair, vaginal repair.**

21 A. Yes. So the title of the article is
22 **"Risk Factors for Prolapse Recurrence After**
23 **Vaginal Repair,"** and what we were interested in
24 **learning, if we could, is in the women who do**
25 **experience recurrence of prolapse, what factors**

1 might be contributing to that.

2 In this article, we found that women of
3 younger age and women with more severe prolapse
4 had a higher risk of experiencing a recurrence
5 than older women and women with less severe
6 prolapse.

7 Q. Okay. But all of the women in this study
8 had surgery for prolapse repair. True?

9 A. Yes.

10 Q. And so we can, for example, see --

11 I'm not going to belabor it at this
12 point, but just to make this point: Here, for
13 example, preoperatively, Stage 2, 49.4% of all the
14 women in the study, so just short of half of them,
15 were Stage 2?

16 A. Actually, this table represents the women
17 who had a preoperative stage of 2 and then a
18 postoperative stage of 0 or 1. That's what the
19 49.4% represents --

20 Q. Okay.

21 A. -- in this table.

22 Q. In this category of those who --

23 And that's a good point. There's
24 actually more than just the 41 there. There's
25 also another 42 that were Stage 2, right?

1 A. After the surgery, that's correct.

2 Q. Before the surgery. Preoperative.

3 Right?

4 A. Oh, I see what you're saying. Okay.

5 Right.

6 So preoperative, Stage 2 --

7 Q. Here, let me make it -- maybe I can cut
8 through some of this and make it easier.

9 A. Okay.

10 Q. Several of those women in that study who
11 were operated on for prolapse were Stage 2 in the
12 beginning, right?

13 A. Yes.

14 Q. One of the things you were look- --
15 This didn't have anything to do with mesh
16 either.

17 A. That's correct.

18 Q. One of the things you were looking at,
19 though, is who has a recurrence and can we figure
20 out what kinds of people, what kinds of
21 preexisting conditions, et cetera, are going to be
22 most likely to result in recurrence down the road.

23 Fair?

24 A. Yes.

25 Q. You also talked about this article, which

1 is Plaintiff's Exhibit 500. That's -- that's
2 another one of yours. True?

3 A. Yes.

4 Q. And which -- what's the date of this?

5 It's '01. This is a little older, but
6 the patients studied in this -- this is the one
7 that looks at three different techniques, and are
8 you also looking to see what the recurrence rate
9 is, or something else?

10 A. Yes.

11 Q. And so you looked at these three
12 different techniques. Again, this didn't have
13 anything to do with the kind of mesh we're talking
14 about in this case. I think it was absorbable
15 mesh of some sort that was used in one of the
16 techniques.

17 A. Yes. You're right.

18 Q. But again, there were patients in these
19 that had -- actually, it says that there were some
20 in Stage 0, but certainly in Stage 1 and Stage 2
21 that were included in this. True?

22 A. Yes.

23 Q. And we could go through probably lots of
24 others, but just the last one here, Exhibit 707.
25 That study also talks about specifically

1 cystoceles. There were 52 of -- out of the 100
2 that were being studied that were Stage -- or,
3 excuse me, Grade 1 and 2?

4 A. Right. And grade and stage are
5 different, and --

6 Q. I knew you were going to tell me that.

7 A. Yes.

8 Q. You're going to educate me on that.
9 They're different how?

10 One of them is the POP and one of them is
11 the -- one of them is -- not POP. POP-Q.

12 A. Yes.

13 Q. Okay. How does that relate? Is a -- is
14 a Grade 1 the same as a Stage 1, or sometimes, or
15 never?

16 A. Sometimes.

17 Q. Okay. Depends on who's doing it,
18 probably? The staging?

19 A. Well, we hope not. That's -- that's the
20 point of having a standardized examination, that
21 if it's performed correctly, it should not vary
22 between examiners.

23 Q. That's with the POP-Q.

24 A. Well --

25 Q. Or staging too?

1 A. Oh, yes. With either, yes.

2 Q. Okay. So if they're doing it right, is a
3 Grade 1 and a Stage 1 going to be the same?

4 A. Not exactly.

5 Q. Tell me, without teaching me the whole
6 class, how they're going to be different. And I
7 don't mean that in a bad way at all, but just kind
8 of short, sweet, and to the point.

9 A. Okay. So in the grading system, which is
10 what's used primarily by clinicians, a Grade 1 is
11 a prolapse that extends roughly halfway down the
12 length of the vagina towards the vaginal opening.

13 Grade 2 is when the prolapse extends to
14 the vaginal opening.

15 Now, in the staging process of POP-Q,
16 Stage 1 actually includes a greater amount of the
17 vaginal length, to within 1 centimeter of the
18 hymen. So it's just above the hymen, which is not
19 exactly the vaginal opening because the vaginal
20 opening is a couple of centimeters away, but
21 anyway, it just extends it to a degree closer to
22 the vaginal opening than the grading does.

23 Does that answer your question?

24 Q. You know, it probably did. I'm not sure
25 I understood it, but --

1 A. I did my best.

2 Q. -- I bet it probably did. That's okay.

3 It's close enough.

4 You talked about the ACOG bulletin. Let
5 me see if I can boil this down.

6 You were involved in the bulletin
7 language that said -- and I'm really
8 summarizing -- using mesh is experimental.

9 A. Using the mesh kits in particular.
10 That's right.

11 Q. They came along -- I say "they."

12 Were you still on that committee when
13 they changed it?

14 A. No, no. I was never a member of the
15 committee on gynecologic practice within ACOG. I
16 was asked by the committee to coauthor this
17 document.

18 Q. They -- they then, the committee, however
19 they did it -- there was some discussion about
20 that -- came along and decided to make changes to
21 it, and understandably you, having written the
22 first one and feeling the way you feel, didn't
23 like it and you wrote a letter saying, "I don't
24 like this, I think it's wrong, for multiple
25 reasons." True?

1 A. That's a paraphrasing, but yes.

2 Q. I understand.

3 A. Yes.

4 Q. You also --

5 You were asked about this. You also,
6 though, do understand there are those out there
7 who did have different opinions and also wrote to
8 the -- a letter to the editor saying basically,
9 "We think the process was followed and we think
10 this is the right way to do it."

11 That happened?

12 A. Any individual to whom you are referring
13 would not have knowledge of the internal processes
14 within ACOG as to how exactly this happened.

15 Q. What if it was Hal Lawrence III? Would
16 he have knowledge of it --

17 A. Well, he's represent- --

18 Q. -- being he was the vice president of
19 practice activities?

20 A. Right. I'm sorry. I didn't know you
21 were referring specifically to the ACOG
22 representative who was responding.

23 Q. Yeah. And here -- my question is just as
24 simple as this, because it seems to me like this
25 is the case, not uncommonly in litigation, that

1 there could be two sides to the story or two
2 arguments and they present their side and the
3 other side presents their position.

4 There is another position that you don't
5 agree with on the issue of the word
6 "experimental." True?

7 A. There is another position, yes.

8 Q. And you don't agree with it. You've made
9 that clear. You don't. Right?

10 A. That's right. I don't agree with that.

11 Q. Then I think I learned this from reading
12 some articles, including a couple that you were
13 the author of. At least at one point in time
14 about 200,000 surgeries are done a year on -- and
15 you're going to correct me, I'm sure, if I get
16 this wrong.

17 Is it 200,000 in the United States or
18 worldwide --

19 A. That is --

20 Q. -- on prolapse and --
21 Which is it?

22 A. Yes, that's -- in the United States.

23 Q. Okay. Which is one of the reasons
24 that -- I assume that there's a lot of literature
25 out there on both sides of the fence discussing

1 lots of things about, you know, what should we be
2 doing, when should we be doing it, what should we
3 use, et cetera. I mean, that's a fair amount of
4 surgeries.

5 A. Yes. You're right.

6 Q. You -- I'm just going to go through these
7 notes here. We're getting close, I think.

8 This is sort of what I started with, but
9 just again, I want to make sure that I've made
10 this clear, if for no other purpose so that I've
11 done my job.

12 A. Uh-huh.

13 Q. These documents, to the extent that
14 you've discussed internal documents of Ethicon --

15 Are you with me?

16 A. Yes.

17 Q. So we've talked about some literature,
18 we've talked about a few things that the doctors
19 may have seen, but to the extent you're talking
20 about internal documents that have details in
21 there -- and I suspect you may be asked about some
22 more here in a little bit -- those are the kinds
23 of things that the doctors like Dr. Simpson, they
24 don't see. True?

25 A. Correct.

1 Q. The one other thing -- well, two more
2 things I think I want to ask you about real quick.

3 Is it still true --

4 Do you remember when your deposition was
5 taken? It was about -- was it April, May,
6 June-ish?

7 A. Which one?

8 Q. In this case.

9 A. I -- June and then December.

10 Q. Okay. In December, you had a
11 supplemental depo and we talked about some other
12 issues that had come up?

13 A. Yes.

14 Q. Is it still true that your only source of
15 earned income is working with Mr. Slater and/or
16 his firm?

17 A. Yes.

18 Q. Okay. And then I think I heard you say
19 earlier today -- and maybe I was confused about
20 it -- that -- you talked about transvaginal mesh,
21 and I think we may have got caught up in the
22 moment of saying all of it is for prolapse.

23 There's actually transvaginal mesh used
24 for non-prolapse purposes that you have used.
25 True?

1 A. Yes.

2 Q. Okay. So the whole idea of taking mesh
3 and putting it through the vaginal wall, up into
4 the -- between -- actually, between the vaginal
5 wall and the -- ureter, isn't it?

6 A. Urethra I think you're referring to --

7 Q. Urethra. You're right.

8 A. -- yes.

9 Q. The whole idea of using that approach,
10 there is at least some time when you think --
11 well, at least there was a point in time when you
12 used it and obviously thought it was appropriate
13 at that time. True?

14 A. At that time.

15 Q. Okay.

16 A. That's not a position I hold any longer.

17 Q. I understand.

18 MR. OVERBY: Doctor, appreciate
19 your time. Thank you.

20 THE WITNESS: Thank you.

21 MR. SLATER: Give me one second to
22 find a paper clip.

23 David, I just needed you to go another
24 minute.

25 MR. OVERBY: You needed me to do

1 what? Go a minute?

2 MR. SLATER: I just needed you to
3 go another minute because I was just trying to
4 find a paper clip for a couple things.

5 JUROR: Here.

6 MR. SLATER: Oh, I'm good.

7 THE COURT: Well, we could stand
8 up and stretch.

9 MR. SLATER: Excellent. Thank
10 you.

11 JUROR: You're welcome.

12 THE COURT: If you run out of any
13 more, here's a whole box of them. They belong to
14 the county, so use what you want.

15 MR. SLATER: I think we're giving
16 the local Staples a lot of business lately. Let
17 me put my stuff up here.

18 REDIRECT EXAMINATION

19 QUESTIONS BY MR. SLATER:

20 Q. Okay. Dr. Weber, you were just asked by
21 Mr. Overby about 200,000 procedures a year to
22 treat prolapse. That's not all with mesh, is it?

23 A. No.

24 Q. Okay. And in terms of the number of
25 procedures dealing with mesh -- being done with

1 mesh today to treat prolapse versus the numbers
2 back in 2008, the numbers are much lower now,
3 aren't they?

4 A. Yes, they are.

5 Q. Okay. We're going to run through these
6 things topically, okay?

7 You talked a lot about anatomic versus
8 functional outcomes, right?

9 A. Yes.

10 Q. And in your 2004 article, you actually
11 published that there needed to be more focus on
12 this subject because you thought that science
13 needed to move more towards functioning on how
14 does the woman feel, how does she do day-to-day,
15 as opposed to just a measurement?

16 A. Yes. That's correct.

17 Q. Okay. And in fact, from 2004 forward,
18 did the scientific community ultimately -- and I'm
19 talking about in the field of urogynecology --
20 ultimately accept that viewpoint?

21 A. Yes.

22 Q. And in fact, did you publish an article
23 in 2011, along with Dr. Chmielewski, Dr. Walters,
24 and Dr. Barber, actually reanalyzing your initial
25 study from 2001 and making that point?

1 A. Yes.

2 Q. And your coauthors, Dr. Barber, he's
3 actually at the -- for the last few years -- I
4 guess he's not anymore -- he was the president of
5 the American Urogynecologic Society and he was
6 your coauthor?

7 A. Yes, that's right.

8 Q. And ultimately also that viewpoint was
9 accepted by ACOG and by AUGS in 2011 in a joint
10 committee opinion, correct?

11 A. Yes.

12 Q. I'm going to talk a little bit about the
13 studies.

14 Ms. Jones asked you quite a bit of
15 questions about randomized controlled trials and
16 that there's been all sorts of studies done on the
17 Prolift. Remember that?

18 A. I remember those questions.

19 Q. And you were asked about the
20 de Landsheere article -- I guess that's the
21 gentleman's last name -- and Cosson was one of the
22 authors?

23 A. Yes.

24 Q. And that was published -- if I can find
25 it in the small type -- in 2011, correct?

1 A. Yes.

2 Q. And ultimately --

3 I don't know if you have a copy there,
4 but I can walk up there and save time.

5 Sometimes when authors publish a study,
6 they will recognize there may be some weaknesses
7 or some issues that would say you might not want
8 to take this all a hundred percent because there
9 were some issues here?

10 A. Yes.

11 Q. Okay. And as you look at the study that
12 Ms. Jones asked you about, in terms of loss to
13 follow-up, was that something that they referenced
14 as a weakness, potentially, because there were
15 patients that they lost track of, they didn't come
16 back, so they don't know what happened to them?

17 A. Yes.

18 Q. Okay. And did they also say that there
19 may be some complications underestimated because
20 some patients didn't have reoperations and that's
21 what they were really focusing on was
22 reoperations?

23 A. Yes, that's right.

24 Q. And ultimately, did the authors at the
25 very end say, "You know, although we think that

1 these results are good for -- for these -- this
2 period of time, we need further long-term
3 follow-up to evaluate this technique in order to
4 decide whether or not it's really something that
5 can -- should be used all the time"?

6 A. Yes.

7 Q. And there's another study that's an RCT
8 that Ms. Jones was asking you about the RCTs,
9 and I just want to ask you a couple questions
10 about one.

11 And, Doctor, this is an article that
12 we've marked as PLT0516 and it's -- it's titled
13 "Trocar Guided Mesh Compared with Conventional
14 Vaginal Repair in Recurrent Prolapse, a Randomized
15 Control Trial."

16 You see that?

17 A. Yes, I do.

18 Q. And with regard to the subject matter in
19 here, is this something that you find has
20 authoritative and reliable information within it?

21 A. Yes.

22 Q. Okay. Now, this was published and this
23 was -- this was a study of the Prolift compared to
24 suture repairs, right?

25 A. Yes.

1 Q. And in fact, the people who authored it
2 studied women for about a year, right?

3 A. Yes.

4 Q. And the people who authored it actually
5 are the -- they have a financial disclosure. Most
6 of them were actually consultants to Ethicon,
7 correct?

8 A. Yes.

9 Q. And this was published in two
10 thousand- -- February 2011, right?

11 A. Yes.

12 Q. And here we have -- on the front page,
13 they have a -- the results, and what was the mesh
14 exposure rate they found in that study with the
15 Prolift?

16 A. Okay. Mesh exposure was detected in 14
17 of 83 patients. 16.9%.

18 Q. And in fact, if we now go to the last
19 page -- and it's Page 250 -- at the very top of
20 the left column, with regard to the subject we
21 talked about about comparing functional results of
22 how women actually do, did they, in fact, find
23 that women pretty much did the same, regardless of
24 whether they had a Prolift or a suture?

25 A. Yes.

1 Q. And --

2 A. Equal improvements.

3 Q. And then at the end, they basically say
4 that the -- "Because the long-term effects and
5 safety of mesh reinforced repairs are not yet
6 fully known, surgeons may consider these
7 procedures primarily for recurrent vaginal
8 prolapse after counseling patients on the risks
9 and benefits."

10 Now, recurrent vaginal prolapse means the
11 woman's already had surgery and then it happened
12 again and you need more surgery, right?

13 A. Yes.

14 Q. That's not Mrs. Budke, correct?

15 A. That's correct.

16 Q. And of course Dr. Simpson couldn't know
17 this. And she was sitting over there before.
18 This is three years after, correct?

19 A. Yes.

20 MS. JONES: Your Honor --

21 THE COURT: Yes, ma'am. Okay.

22 MS. JONES: -- I know we're trying
23 to finish and I don't mean to interrupt but I
24 don't believe that the leading is appropriate so I
25 object to continuing with leading.

1 THE COURT: Okay.

2 MR. SLATER: Okay. I'm sorry. I
3 was --

4 THE COURT: Yeah. I know you were
5 trying to expedite it, but let's don't lead.

6 MR. SLATER: That's no problem.

7 THE COURT: I don't want to get
8 back into that.

9 MR. SLATER: That's no problem.

10 THE COURT: Okay.

11 Q. (By Mr. Slater) So anyway, this
12 conclusion we're talking about, in terms of
13 recurrent prolapse, did, in fact -- did the TVM
14 group, in their 2004 article, actually address
15 that issue too?

16 A. Yes, they did.

17 Q. And was it similar?

18 A. Yes.

19 Q. Okay. I'm showing you a article we've
20 marked as PLT0227 titled "Vaginal Mesh for
21 Prolapse, a Randomized Controlled Trial."

22 Is this an article you're familiar with?

23 A. Yes.

24 Q. And is this something you find to be
25 authoritative in the field?

1 A. Yes.

2 Q. And it's authored by Dr. Iglesia and some
3 others, correct?

4 A. Yes.

5 Q. And in this study, it was studying the
6 Prolift compared to suture repairs?

7 A. Yes.

8 Q. And what was the erosion rate that these
9 doctors found with the Prolift?

10 A. 15.6%.

11 Q. And were these doctors connected to
12 Ethicon?

13 A. No.

14 Q. And when they got an erosion rate at
15 15.6%, what did they do?

16 A. The study protocol defined in advance a
17 threshold for safety, and if the mesh erosion rate
18 exceeded 15%, they would stop the study, and in
19 fact, that's what they had to do.

20 And by stopping the study, just to be
21 clear, that means that --

22 Q. Nothing else.

23 THE COURT: Whoa, whoa.

24 THE WITNESS: Oh, I'm sorry. I
25 just --

1 THE COURT: Yeah. Remember, we're
2 not teaching now. We're answering questions.

3 THE WITNESS: I just didn't want
4 the jury to be --

5 THE COURT: That's all right.

6 MR. SLATER: I'll ask another
7 question.

8 THE WITNESS: Okay. I'm sorry.

9 MR. SLATER: I'll ask another
10 question.

11 Q. (By Mr. Slater) Did they continue to
12 follow the women who had already been operated on?

13 A. Yes, they did.

14 Q. Okay. They just didn't operate on any
15 more women going forward?

16 A. Exactly.

17 Q. Okay. Meaning they didn't put any more
18 Prolifts in women's bodies?

19 A. That's right.

20 Q. Okay. I've marked as PLT0629 an abstract
21 from -- that says -- Abstract Number 121 from a
22 medical conference.

23 Are you familiar with this?

24 A. Yes.

25 Q. And with regard to the information found

1 in it, do you find it to have authoritative and
2 reliable information that you can rely on?

3 A. Yes.

4 Q. Now, this -- this abstract, what is it
5 telling us about?

6 A. This is a retrospective review from the
7 French TVM group reporting on the use of the
8 Prolift mesh in 687 patients.

9 Q. And just to be clear, this was from 2005,
10 so it was the mesh used in the Prolift but it
11 wasn't the Prolift kit. It was the Gynemesh they
12 were using.

13 A. That's correct.

14 Q. Okay. And the follow-up period was how
15 long for these women?

16 A. 3.6 months.

17 Q. Would that be considered very short-term?

18 A. Very short-term.

19 Q. And if we look at the interpretation of
20 the results --

21 And the authors are people from the
22 group? Cosson, Jacquetin, and the rest?

23 A. Yes.

24 Q. Look at the very end, the "Interpretation
25 of Results," and what was the erosion rate that

1 **they reported at 3.6 months?**

2 A. Okay.

3 **Q. At the very bottom of the page. Very**
4 **last sentence.**

5 A. Yes. 6.7%.

6 **Q. And what did they consider that to be, in**
7 **terms of defining 6.7%?**

8 A. They considered that was high regarding
9 the impairment that granulation formation and
10 vaginal erosion would cause.

11 **Q. In 2005, that's the -- that's when the**
12 **Prolift was put on the market?**

13 A. Yes.

14 **Q. Okay. And if you look at the concluding**
15 **message on the next page, with regard to the**
16 **erosion rates, based on this, what was the -- what**
17 **was the definition of how they described those**
18 **rates?**

19 A. They described those rates as
20 significant.

21 **Q. And the recurrence rates, how did they**
22 **describe those?**

23 A. The recurrence rates were described as
24 disappointing.

25 **Q. Doctor, you were asked about the TVM**

1 study, the French TVM study, and I'm not going to
2 bother to put it up on the board. I think we all
3 know it. I think we've talked about it.

4 The confidence intervals in that study,
5 were they chosen by Ethicon?

6 A. Yes.

7 Q. Okay. And is that something that's
8 normally done in a study like this where you do a
9 study on a certain number of women but you want to
10 know what the wider impact is so you want to say,
11 "Well, we want to be able to translate these
12 results to more people so we have an idea how this
13 will affect more people"?

14 A. Yes.

15 Q. Okay. And that's what they did here?

16 A. Yes.

17 Q. Based on the criteria Ethicon set, did
18 the results of the French TVM study show a success
19 or a failure of the primary thing being studied?

20 A. A failure.

21 Q. Now, you were asked about the protocol
22 deviations where there were some women that were
23 operated on with Stage 2s even though they
24 weren't supposed to be?

25 A. Yes.

1 **Q. The bottom line was they weren't supposed**
2 **to be operated on by this study, right?**

3 A. That's correct.

4 **Q. And the protocol deviations were because**
5 **the people examining them didn't know how to do**
6 **the POP-Q measurements correctly?**

7 MS. JONES: Objection, Your Honor.

8 MR. SLATER: I'll ask it
9 differently. Apologize.

10 THE COURT: I sustain that.

11 **Q. (By Mr. Slater) What was the reason for**
12 **the protocol deviation?**

13 A. In many cases, the POP-Q had been done
14 incorrectly, resulting in -- in measurements
15 adding up to stages that were not allowed in the
16 study by protocol.

17 **Q. And in terms of the final data, and when**
18 **you reviewed the internal documents about the data**
19 **collection, were there any issues with the POP-Q**
20 **measurements in accumulating the final data?**

21 A. Yes.

22 **Q. What was that issue?**

23 A. The same issue, where measurements were
24 made that were outside of the definition of the
25 measurement so that it could only range, say, from

1 minus 3 to plus 3, but someone would record a plus
2 5, which is outside the definition, so it's
3 impossible.

4 And since this was the outcome they
5 relied on, with having so many problems with the
6 POP-Q measurements, the overall failure rate
7 anatomic recurrence becomes unreliable. It could
8 be much worse.

9 MR. SLATER: I have a couple short
10 PowerPoints I want to use. I want to ask
11 Ms. Jones if I could just show them to you real
12 quick. We made them up over the lunch hour. I
13 don't want to put it up without showing her.

14 THE COURT: Yeah. I don't want
15 you to. I don't need to gnaw at that, so just
16 y'all go look at it.

17 MS. JONES: May we approach, Your
18 Honor?

19 THE COURT: Sure.

20 (Counsel approached the bench and
21 the following proceedings were held outside the
22 hearing of the jury:)

23 MR. SLATER: Judge, if you can see
24 what he can put up on the screen, we could show
25 you what it looks like without putting it up on

1 there. We can put it up --

2 THE COURT: He can put it on
3 where? On this (indicating)?

4 MR. SLATER: Yeah. You get the
5 same thing that the witness gets on the TV screen.
6 Whatever comes up on there comes up on your
7 screen.

8 Okay. They say no so --

9 THE COURT: No?
10 What did you start to say?

11 MS. JONES: Well, I object to the
12 use of the PowerPoints that he intends to put up.
13 Let me see if I can describe what he intends to
14 put up.

15 THE COURT: All right.

16 MS. JONES: He intends to put up a
17 PowerPoint with 35,000 women, and then to take it
18 and take 20% of those would be X and 20% of -- I
19 mean, 20% of those would be a recurrence, and he's
20 got the number there, and then he's got an erosion
21 rate and he shows the number there.

22 That's an inappropriate use of that
23 document and it's simply argument, inappropriate
24 for redirect, and I think beyond the scope of
25 redirect. The scope of redirect --

1 THE COURT: I'll buy it on the
2 scope of redirect. Not otherwise. But on the
3 scope, that it does beyond --

4 MR. BALL: Thank you.

5 THE COURT: -- your examination.

6 MS. JONES: Thank you.

7 MR. SLATER: Okay. I'll save it
8 for later.

9 THE COURT: Yeah. All right.

10 (The proceedings returned to open
11 court.)

12 THE COURT: Get rid of that.

13 Q. (By Mr. Slater) Okay. Dr. Weber,
14 remember you were asked by counsel about the fact
15 that the TVM group and the doctors who did the TVM
16 study -- I guess it was U.S. and France --
17 ultimately published their results in the
18 peer-reviewed literature and said, you know, "We
19 think this proves we -- this should be used"?

20 A. Yes.

21 Q. Remember those questions?

22 A. Yes, I do.

23 Q. I'm going to show you one of those
24 articles and it's PLT0335, and this is an article
25 titled "Prospective Clinical Assessment of the

1 **Transvaginal Mesh Technique for Treatment of**
2 **Pelvic Organ Prolapse, Five-Year Results," right?**

3 A. Yes.

4 Q. And who are the authors of that article?

5 A. Dr. Miller, Dennis Miller; Dr. Vincent
6 Lucente; Dr. Elizabeth Babin; Patricia Beach;
7 Peter Jones; and David Rob- -- Dr. David Robinson.

8 Q. And who would have chosen the authors and
9 said, "Okay, these could be the people put on this
10 study as the authors"?

11 A. Ethicon would do that.

12 Q. Okay. And this was published when? What
13 year?

14 A. This was published in 2001.

15 Q. 2001 or --

16 A. Oh, I beg your pardon. 2011.

17 Q. Okay. And as of 2011, in Ethicon medical
18 affairs, and with regard to Dr. Lucente publishing
19 data, were there any concerns?

20 A. Yes. There were grave concerns about the
21 veracity of Dr. Lucente's data when published.

22 MS. JONES: Objection, Your Honor.
23 Beyond the scope of redirect.

24 THE COURT: What?

25 MS. JONES: Let's approach.

1 THE COURT: All right.

2 (Counsel approached the bench and
3 the following proceedings were held outside the
4 hearing of the jury:)

5 MS. JONES: This paper was not
6 discussed.

7 MR. SLATER: It was referenced
8 generally. Counsel said that the TVM group and
9 all these studies were put out by Ethicon talking
10 about how safe the Prolift was proven to be by
11 their studies. This is the paper on the TVM study
12 and they put Lucente on it as an author reporting
13 the data, and we know that the company thought he
14 was publishing false data at that point.

15 MS. JONES: Yeah, but you can't --

16 MR. BALL: Whoa. This is like
17 three steps removed from our --

18 THE COURT: I'm going to go along
19 with the objection on it.

20 MR. SLATER: Okay.

21 MS. JONES: I'm sorry, Your Honor.
22 I --

23 MR. SLATER: I'm not going to ask
24 any more questions. No more questions on that.

25 THE COURT: All right.

1 (The proceedings returned to open
2 court.)

3 Q. (By Mr. Slater) Okay. Moving right
4 along, remember you were asked some questions,
5 Dr. Weber, about whether something's published,
6 and I think you said words to the effect of the
7 journals have to rely on the honesty of the
8 authors?

9 A. Yes.

10 Q. And I'm going to just give you something
11 and ask you a question about it, and it's Exhibit
12 P2672.

13 A. Thank you.

14 Q. And what is this document?

15 A. This is a publication in the American
16 Journal of Obstetrics and Gynecology where the
17 editors are informing their readership that an
18 article has been retracted and the reasons for
19 that retraction.

20 MS. JONES: Your Honor, I'm going
21 to object to this as totally irrelevant and beyond
22 the scope. I'm -- this --

23 MR. SLATER: Dr. Weber was
24 asked --

25 MS. JONES: This does not --

1 THE COURT: Let me look at the
2 thing. Let me look at that.

3 MR. SLATER: Yeah. Sure.

4 (Counsel approached the bench and
5 the following proceedings were held outside the
6 hearing of the jury:)

7 THE COURT: Wait a minute. I
8 haven't put on the silence yet. I just want to
9 read this first.

10 Okay. What's your problem with this?

11 MS. JONES: I object to it, one,
12 because it's totally beyond the scope. Two, it
13 doesn't deal with any of the articles that we're
14 talking about.

15 MR. BALL: Isn't it hearsay?

16 MS. JONES: Three, it is hearsay.

17 THE COURT: Did we ever talk about
18 the original article that --

19 MS. JONES: No.

20 MR. SLATER: No, we didn't. I
21 just want a chance to argue after her.

22 MS. JONES: The last thing is that
23 we can't extend the scope of redirect because of
24 some voluntary statement that Dr. Weber made when
25 we were on cross-examination.

1 THE COURT: Well, yeah. She's
2 made a lot of them and so have other people, but
3 anyway, here's the whole thing. If the
4 original -- if the original thing was not put in
5 evidence, then I'm not going to allow this in as a
6 criticism of something I don't know about.

7 MR. SLATER: I was just -- okay.
8 I was going to let you know why, but okay.

9 THE COURT: Oh, I think -- okay.
10 Go ahead.

11 (The proceedings returned to open
12 court.)

13 Q. (By Mr. Slater) Okay. Dr. Weber, do you
14 have the monograph up there? The document that
15 you were asked about for a while today?

16 A. I should. Let me put my hands on it.

17 Okay. Yes.

18 Q. Okay. Now, you were shown some documents
19 and some information by Ms. Jones during your
20 cross-examination, right?

21 A. Yes.

22 Q. And they were documents like the
23 monograph and the IFU, and you were asked
24 questions about the warnings. Remember that?

25 A. Yes.

1 **Q. Having heard everything Ms. Jones asked**
2 **you, as you stand here now, what is your opinion**
3 **as to whether or not the Prolift is a defective**
4 **and unreasonably product and dangerous [sic] due**
5 **to the inadequate warnings?**

6 MS. JONES: Your Honor, I object
7 as improper redirect.

8 MR. SLATER: I just want to
9 reiterate --

10 MR. BALL: The purpose of redirect
11 is not to repeat things that were said on direct
12 examination.

13 MR. SLATER: I'm sorry, Your
14 Honor.

15 THE COURT: Have you changed your
16 opinion from a few minutes ago where you said
17 it -- or back this morning where you said it was
18 no good? Have you changed your mind?

19 THE WITNESS: No, I haven't, Your
20 Honor.

21 THE COURT: All right then.
22 That's good enough. We don't need to retrack
23 that.

24 **Q. (By Mr. Slater) Okay. Now, you were**
25 **asked about 200 surgeons giving information. I**

1 want to try to -- I think there was a disconnect.

2 I want to try to focus on where we are and move
3 forward.

4 A. All right.

5 Q. In this monograph, they talk about
6 surgeons having attended forums.

7 A. Yes.

8 Q. To your knowledge -- well, let me -- I'll
9 jump ahead, actually.

10 We don't have documentation of what those
11 surgeons actually told Ethicon, right?

12 A. That's right. We don't.

13 Q. We know what Ethicon says they learned
14 when they spoke to them, and we have Ethicon's
15 version of what they learned, right?

16 A. Yes.

17 Q. And the important thing is that Ethicon
18 accurately represent information in its own
19 documents, right?

20 A. That would be -- that would be important
21 if that were the case.

22 Q. Now, what I'd first like to do is turn to
23 the first page of it, Page 1, and look at who
24 authored this and you see it right in the
25 foreword, the first paragraph? There's a series

1 of people?

2 A. Yes.

3 Q. I don't know the exhibit. You don't have
4 to. Don't bother it. We'll move faster this way.

5 And one of them is Vince Lucente?

6 A. Yes.

7 Q. And in the second paragraph, about four
8 lines down, there's a sentence that starts right
9 in the middle of the line, "This document is an
10 open exchange of ideas representing the most
11 up-to-date information possible."

12 That's what Ethicon told people?

13 A. Yes.

14 Q. And a little further down, it says -- two
15 lines from the bottom of that paragraph -- that
16 the information is honestly presented, right?

17 A. Yes.

18 Q. Let's go just a little further down.
19 Down in the first paragraph -- not the first.
20 One, two, three -- the fifth paragraph. Sorry
21 about that.

22 A. Okay.

23 Q. And it talks about a recent study
24 published in Obstetrics and Gynecology by the
25 Nordic -- what do they call themselves? The

1 Nordic Transvaginal Mesh Group.

2 You see that?

3 A. Yes, I do.

4 Q. And it says that they -- their study
5 demonstrated the rate of peri-operative
6 complications with the Gynecare Prolift system is
7 very low.

8 That's what's represented in this
9 document, right?

10 A. Yes, that's what it says.

11 Q. Okay. I'm going to bring you the actual
12 article now. PLT0030. Let's see what they said
13 in the article.

14 This is titled "Peri-Operative
15 Morbidity" -- PLT00- -- oh, you can't put it up.
16 Don't worry about it. "Peri-Operative Morbidity
17 Using Transvaginal Mesh in Pelvic Organ Prolapse
18 Repair." The authors are Altman, Falconer for the
19 Nordic Transvaginal Mesh Group, right?

20 A. Yes.

21 Q. 2007, right?

22 A. Yes.

23 Q. And there's a financial disclosure down
24 in the left that Dr. Altman and Falconer are
25 consultants to Ethicon?

1 A. Yes.

2 Q. Okay. And what I want to do is just kind
3 of skip along through this.

4 They're studying peri-operative outcomes.
5 That would be from the surgery and the very short
6 time after?

7 A. Correct.

8 Q. And let's skip forward all the way to
9 Page 307.

10 And just to orient ourselves again, this
11 is the study that Ethicon represented proved that
12 the peri-operative complications are very low --

13 A. Yes.

14 Q. -- right?

15 A. Correct.

16 Q. In the top left, the first full
17 paragraph, tell me if I read this right.

18 "Close to 15% of our patients experienced
19 what we characterized as minor complications."

20 MS. JONES: I'm going to stop --

21 THE COURT: Okay. Do you have
22 a --

23 MS. JONES: -- ask counsel to
24 stop. I believe it's hearsay and I think he's
25 read what he wants to to the jury, but I think --

1 THE COURT: Well, was this -- was
2 this spoken of in direct examination?

3 MS. JONES: No.

4 MR. SLATER: Can we approach?
5 It's referenced in the document counsel used.
6 It's referred to and they claim it said one thing
7 and I'm showing that it said something else.

8 MS. JONES: It did not.

9 MR. SLATER: Of course it did.
10 It's in the document you used, Counsel.

11 THE COURT: Let's look. Let's go
12 back on here, if it is, and we'll let him do it.
13 If it's not, that's it.

14 MR. SLATER: It's this paragraph
15 right here (indicating), Your Honor.

16 THE COURT: Let's --

17 MR. SLATER: It refers to a recent
18 study right there (indicating). I circled it.
19 That's this article.

20 (Counsel approached the bench and
21 the following proceedings were held outside the
22 hearing of the jury:)

23 MR. BALL: Is this as far as
24 you're going to go with it?

25 MR. SLATER: No. I'm going to

1 bring out all the stuff, the detail.

2 MS. JONES: My objection, Your
3 Honor --

4 MR. SLATER: Can we come over here
5 because this time I'm hoping to get a chance to
6 argue this time.

7 THE COURT: All right.

8 MS. JONES: My objection, Your
9 Honor, is he's simply sitting up there reading the
10 article. It's hearsay.

11 THE COURT: Yeah.

12 MS. JONES: It's back to the same
13 issues that we had the other day about whether or
14 not he could ask her opinion and elicit it.

15 Now, he said 15% of minor complications.
16 You know, that's what he wanted to put up there.
17 He's gotten it in there.

18 MR. SLATER: This is what I --
19 I'll tell counsel what I was going to do.

20 THE COURT: Okay.

21 MR. SLATER: Okay. First of
22 all -- and I'd like to preface this. I respected
23 what you said, obviously, and I spoke to my expert
24 and I told her stop doing it --

25 THE COURT: Yeah.

1 MR. SLATER: -- because Your Honor
2 told us we'd get plenty of room on redirect.

3 THE COURT: Well, here's the whole
4 thing. Look, I'm trying to be fair here. Every
5 time you turn around, you say "Now those are
6 consultants to Ethicon, aren't they? Those are
7 consultants to Ethicon, aren't they?"

8 You know, if they want to say it and say,
9 "You're a consultant to Mr. Slater, aren't you?
10 You're a consultant to Mr. Slater, aren't you?" --

11 MR. SLATER: They've done it.
12 They've done it.

13 THE COURT: They've done it to
14 some extent, but I thought they were pretty easy
15 on that.

16 MR. BERGMANIS: She let her
17 testimony weigh in, though, and now she ought to
18 be able to explain it on redirect.

19 MS. JONES: I'm not -- I'm not --

20 MR. SLATER: Can I finish, please?
21 Pretty please? With sugar on top? I was going to
22 try and be nice.

23 MS. JONES: I'm objecting on the
24 basis of hearsay and the way it's been presented
25 in terms of -- if you're going to talk about what

1 you're going to do --

2 MR. SLATER: What I was going to
3 do is I was going to present the article. I read
4 the first sentence to orient her, and then I'm
5 going to have her read the rest to herself and
6 then ask her --

7 THE COURT: Okay. You can ask her
8 if she agrees or disagrees with that, but --

9 MR. SLATER: -- what her opinion
10 is as to whether or not in the monograph they
11 accurately disclosed the information here and let
12 her go that.

13 They actually stood up and said this is
14 how --

15 MR. BALL: Your Honor --

16 MR. SLATER: Please, Dan.

17 They used this document and said this is
18 a document where doctors got warnings about the
19 product that were adequate, and I'm proving right
20 now that they cited a study in a misleading way
21 and I have the right to do that, I think, with all
22 due respect, and I think Don Budke has the right
23 to have me show that to the jury when his wife
24 died from this.

25 MS. JONES: And I think I have the

1 right then to come back --

2 MR. SLATER: Shouldn't have used
3 the document.

4 THE COURT: What's that? What?

5 MS. JONES: If he is misusing the
6 document and misusing this, I think -- I mean,
7 we're just getting into a whole 'nother issue.

8 MR. SLATER: I'm not misusing
9 anything. I'm showing that the article that you
10 cited doesn't say what they said it said.

11 MR. BALL: That's going to lead to
12 a lot of recross by us. Okay?

13 THE COURT: I know it is.

14 MR. SLATER: No, it's not.

15 THE COURT: Well, maybe not okay.
16 Well, try to make it short and sweet.

17 MR. SLATER: I was. I would have
18 been done already.

19 THE COURT: Okay. Okay. We'll
20 see.

21 (The proceedings returned to open
22 court.)

23 Q. (By Mr. Slater) Dr. Weber --

24 A. Yes.

25 Q. -- looking in the top left paragraph

1 where I just started off to situate you --

2 A. Yes.

3 Q. -- in looking at the information there
4 and looking at what Ethicon said in their honest
5 information about the Prolift where they cited
6 this article, do you have an opinion as to whether
7 or not the information in the -- in the monograph
8 accurately represents the information there in
9 that paragraph?

10 A. Yes, I have an opinion.

11 Q. And what's your opinion?

12 A. My opinion is that the Ethicon monograph
13 in no way accurately represents the level of
14 complications reported in this study.

15 Q. And what about the severity of the
16 complications?

17 A. It also doesn't represent the severity of
18 the complications reported in this article.

19 Q. And do they talk about complications
20 having a considerable impact on quality of life
21 and daily function?

22 MS. JONES: Objection. Hearsay,
23 Your Honor.

24 THE COURT: Sustained.

25 Q. (By Mr. Slater) Differently, what is of

1 **significance to you in this article that makes you**
2 **say what you said and give that opinion?**

3 A. That they reported complications that
4 not -- no -- that were medically significant in
5 terms of being dangerous unless they were
6 adequately treated, and also complications that
7 would interfere with a woman's well-being and
8 quality of life.

9 Q. Okay. Let's skip ahead now. In
10 paragraph -- at Page 4, let's look at Page 4,
11 there's a section "Anesthesia and
12 Hydrodissection."

13 A. Yes.

14 Q. And right in the middle of that
15 paragraph, it talks about how to do this procedure
16 on the Prolift system, and it refers to the low
17 rates of mesh exposure seen by experienced
18 Gynecare Prolift system users.

19 Do you see that?

20 A. Yes, I do.

21 Q. And do you have an opinion as to whether
22 that is an accurate statement or not as to the --
23 whether or not the mesh exposure rates were low?

24 A. Yes, I do have an opinion.

25 Q. And what is that?

1 A. My opinion is that mesh exposure rates,
2 even in the hands of experienced Prolift users,
3 were not low.

4 Q. Let's go now to Page 5.

5 Page 5, "Mesh Handling." And actually,
6 I'm going to skip over that in the interest of
7 time. Let's go to the next page.

8 Here we go. Go to Page 8, please.

9 A. Okay.

10 Q. This is the section on "Mesh
11 Complications: Erosion, Exposure, and Extrusion"?

12 A. Yes.

13 Q. Okay. And in there, they make certain
14 representations with regard to the nature of the
15 complications of erosion and they say there,
16 "Intervention is usually quite minimal with local
17 excision under sedation"?

18 A. Yes.

19 Q. "Symptoms are generally mild, ranging
20 from spotting" and a few other minor things?

21 A. Yes.

22 Q. And what I'd like to do now is show you
23 an article we've marked as PLT0067. And are you
24 familiar with this article, PL- --

25 MS. JONES: Your Honor --

1 MR. SLATER: Counsel doesn't know
2 what I'm going to ask.

3 THE COURT: Have a chance to look
4 at it? I'll give you a chance.

5 MS. JONES: May we approach?

6 MR. SLATER: Can I go till maybe
7 I --

8 THE COURT: Yeah.

9 (Counsel approached the bench and
10 the following proceedings were held outside the
11 hearing of the jury:)

12 MR. SLATER: Judge, you want to
13 tell me what I'm going to do?

14 MS. JONES: Doesn't matter what
15 you're going to do. This is a 2008 --

16 MR. SLATER: Doesn't matter what
17 I'm going to do? Got to have something. Got to
18 tell the judge what I'm planning to do, don't I?

19 THE COURT: Okay. Go ahead. Tell
20 me.

21 MR. SLATER: Can I step in?

22 THE COURT: Yeah.

23 MR. SLATER: This was an article
24 that was published in early 2009, and it was
25 presented to the medical affairs corporate

1 representative, and the language I'm going to ask
2 Dr. Weber about, he testified they knew those
3 complications would happen when the Prolift was
4 first marketed, and that testimony is established
5 testimony by Dr. Piet Hinoul.

6 So what I'm going to do is I'm going to
7 use the language, and I'm going to use that
8 language because there are very serious mesh
9 erosion complications the company knew about, as
10 opposed to what they're saying here about easily
11 treated and minor. And I don't -- and, Your
12 Honor, you told me on redirect to go through this
13 and I really would appreciate the chance to be
14 able to show that this monograph that she relied
15 on for most of her cross is a false document.

16 MS. JONES: Well, with all due
17 respect, it's not a false document, Your Honor.
18 If he wants to ask her about that, that's fine.

19 This article is beyond the scope of
20 redirect. It's a 2009 article. You can't use
21 this to go back and ask him about what's in that
22 in 2007, which is when that was done.

23 MR. SLATER: I have a solution. I
24 have a solution.

25 THE COURT: All right. Give me

1 the solution.

2 MR. SLATER: Please, just wait. I
3 have a solution.

4 THE COURT: We got another -- he'd
5 like to weigh in.

6 MR. SLATER: Hear my solution
7 first.

8 This is what I'm going to do: I'm going
9 to make statements of certain levels of
10 complications. They're the ones described in
11 here. But I'm not going to read the article. I'm
12 just going to say "Was Ethicon aware of these
13 types of complications and are they described in
14 the monograph."

15 They've already admitted they knew them.
16 It's not in dispute. So I'm going to have to be
17 able to show the jury that Ethicon knew of more
18 serious complications and then -- than what is
19 here, and in fact, when they talk about something
20 being hearsay, Your Honor, I'm not offering it for
21 the truth. I'm offering it to show notice. Which
22 is -- which means that it's not a hearsay purpose.
23 But I'll do it outside the article but I have to
24 be able to ask her about the more serious
25 descriptions of the complications the company has

1 acknowledged knowing.

2 I don't know how else I can do it and
3 they have a right to show this document to the
4 jury and I can't get around to showing -- showing
5 where the truthful information is?

6 MS. JONES: Your Honor, I'm going
7 to say simply that it is one, cumulative.

8 Two, she's testified that she --

9 MR. SLATER: What? I didn't hear.
10 Cumulative?

11 MS. JONES: Cumulative.

12 She's testified that she doesn't think
13 it's right and they're not entitled to go through
14 this. She's not entitled to go through Ethicon's
15 knowledge. It's beyond the scope of redirect. If
16 he wants to ask her whether or not she thinks that
17 the --

18 MR. BERGMANIS: It's not beyond
19 the scope.

20 MR. SLATER: How can it be beyond
21 the scope of redirect? You used this document to
22 show that doctors were adequately warned.

23 (Court reporter interruption.)

24 MR. SLATER: They used the
25 monograph and represented to the jury that that's

1 an adequate document providing notice to doctors.
2 I have -- I didn't use it, but on redirect if they
3 bring in the document, I have a right to fully
4 have a wide berth on redirect to show that the
5 document's not providing the accurate information
6 they said. Of course I didn't use all this on
7 direct because I didn't go on it. I didn't attack
8 the monograph. I didn't have time. But they
9 opened the door. They put the document in. I
10 have the right to fully explore it.

11 MS. JONES: That has nothing to
12 do --

13 MR. OVERBY: May I --

14 THE COURT: Yes.

15 MR. OVERBY: May I speak?

16 THE COURT: Yes, you may.

17 MR. OVERBY: You are all tired and
18 been here a long time and are going to be here a
19 long time and here's my suggestion.

20 To the extent that this document
21 specifically talks about complications -- we've
22 been over this in this case several times --

23 THE COURT: Oh, yeah.

24 MR. OVERBY: -- beyond those which
25 are at issue in this case, and I think it is

1 inappropriate for that reason.

2 MR. SLATER: Well --

3 THE COURT: What --

4 (Court reporter interruption.)

5 THE COURT: Yeah, I understand.

6 All right. You -- whoa, whoa. You.

7 MR. OVERBY: That's my comment.

8 So he says he's not going to do that, so --

9 MR. SLATER: No. I agree with
10 that a hundred percent.

11 MR. OVERBY: I just wanted to make
12 sure that we don't plow through a whole bunch
13 of -- because that just lengthens it. That's all.

14 THE COURT: I know. Yes, sir.

15 MR. BALL: We've spent two days
16 having her talk about complications. If there's
17 anything that's cumulative, it's complications,
18 and he's just piling on, piling on, piling on.
19 And I don't care if it's a brand-new document. He
20 can't --

21 It is a brand-new document. I agree.
22 It's a brand-new document. It's beyond the scope
23 of doing -- of cross -- it's beyond the scope --
24 we didn't bring up that -- anything about this
25 document and it's just piling on, piling on,

1 piling on with new stuff now on redirect.

2 THE COURT: All right. Let's get
3 on down the road. Huh-uh. No. I'm not going to
4 do that. I think you've got plenty in there
5 already.

6 MR. SLATER: Okay.

7 THE COURT: And you're going to
8 have your chance.

9 MR. SLATER: I'm not, though.
10 This is it.

11 (The proceedings returned to open
12 court.)

13 THE COURT: All right. What next?

14 Q. (By Mr. Slater) Simple question.

15 Their description of erosion here, in
16 your opinion, knowing what you know, does that
17 match Ethicon's knowledge at the time about the
18 scope and severity of erosion complications?

19 A. No, not at all.

20 Q. Thank you.

21 THE COURT: All right.

22 Q. (By Mr. Slater) Let's go to Page 10.

23 There's a chart of clinical data summary.

24 You see that?

25 A. Yes, I do.

1 Q. And for what reason would Ethicon be
2 putting a chart of clinical data in this monograph
3 to be shown to doctors?

4 MS. JONES: Objection, Your Honor.
5 Calls for speculation, state of mind.

6 Q. (By Mr. Slater) What's the purpose of
7 putting clinical data summaries in the Prolift
8 monograph? What is the functional purpose of
9 giving doctors this data?

10 THE COURT: I'll let you ask that
11 one question but we're not going to just keep
12 going and going and going on it, so go ahead.

13 A. The purpose is to inform doctors of the
14 range and frequency of the kinds of complications
15 that have occurred.

16 Q. (By Mr. Slater) The first one across the
17 top is Cosson, et al., 90 patients. Right?

18 A. Yes.

19 Q. That's the French TVM group study, right?

20 A. Yes.

21 Q. The rates of exposure and success stated
22 there, in your opinion are they accurate or
23 inaccurate?

24 A. They are inaccurate.

25 Q. Do they tell about less complications or

1 more?

2 A. Less.

3 Q. If you go down to the third one, it says
4 "Murphy, et al."

5 You see that?

6 A. Yes, I do.

7 Q. And the coauthor with Murphy would be who
8 on that study?

9 A. Dr. Lucente.

10 Q. And what's the exposure rate they say
11 there?

12 A. Zero.

13 Q. At that time, did --

14 Well, let me ask you this: Does Ethicon
15 believe that to be an accurate statement of his
16 exposure rate?

17 THE COURT: I'll sustain your
18 objection before you get it out because that's
19 Ethicon's state of mind and I don't know that
20 and -- no.

21 MR. SLATER: I could offer you
22 deposition testimony on that specific question,
23 Your Honor.

24 MS. JONES: Objection, Your Honor.
25 That's inappropriate.

1 THE COURT: No. No. Go ahead.

2 Go ahead, but just stay out --

3 MR. SLATER: Can I just approach
4 on this because I think there's just something to
5 fix it with, then. I just want to make sure
6 because Dr. Weber is going to leave. I just want
7 to know that I can do something else. Because we
8 won't have a chance to talk about it after.

9 (Counsel approached the bench and
10 the following proceedings were held outside the
11 hearing of the jury:)

12 THE COURT: Let's try one at a
13 time and we'll start with you.

14 MR. SLATER: Thank you, Judge.
15 Dr. Hinoul is an Ethicon witness, a medical
16 affairs corporate representative. Okay? He's the
17 witness they put up for the company in all these
18 cases in the country.

19 THE COURT: She's talked about him
20 and all the rest of it.

21 MR. SLATER: I understand, and let
22 me tell you what he said.

23 He said in the document -- and in
24 testimony he admitted he meant this -- that when
25 Lucente and his group report that they have no

1 erosions, nobody believes that, okay? That's
2 testimony.

3 It's testimony that was agreed to in the
4 federal trial in Bellew in front of Judge Goodwin
5 and now they're going to make an objection to you
6 on that testimony. So I want it -- so if
7 Dr. Weber can't say it, then I need to know that
8 they're going to -- that the testimony is going to
9 come in so the jury can see what Hinoul said
10 because he said nobody believes Lucente's data
11 when he says zero erosions. I have to have a
12 right to get it in one way or the other.

13 MS. JONES: Dr. Hinoul has
14 explained exactly what that meant. He's got the
15 testimony.

16 MR. SLATER: And we should play
17 it. I'm fine with that.

18 MS. JONES: He's got the
19 explanation and he's got the email and that's
20 fine.

21 THE COURT: We can do it that way.

22 MR. SLATER: As long as it's
23 coming in, I don't have to ask that question then.

24 THE COURT: As to that thing, I'll
25 let you play that later on, okay? And that will

1 take care of that.

2 MR. SLATER: Yeah. Thank you,
3 Judge. That saved me from doing this. Okay.

4 (The proceedings returned to open
5 court.)

6 Q. (By Mr. Slater) Moving right along,
7 Dr. Weber, you were asked some questions about
8 Gynemesh Prolene Soft and the use of Gynemesh to
9 be put through the vagina to do a transvaginal
10 mesh repair, right?

11 A. Yes.

12 Q. And as we sit here now, is Gynemesh
13 Prolene Soft indicated by Ethicon to be put in
14 through the vagina?

15 A. No. No, they changed the indications to
16 restrict it to abdominal implantation only.

17 Q. Now --

18 MR. BALL: We have to approach the
19 bench now.

20 THE COURT: Yes. One question
21 caused a lightning strike.

22 MR. SLATER: I'm down to one more
23 question.

24 (Counsel approached the bench and
25 the following proceedings were held outside the

1 hearing of the jury:)

2 MR. BALL: Your Honor, this is --

3 he just violated the court order that --

4 MR. SLATER: I did not.

5 MR. BALL: Yes, you did.

6 He just violated the court order you gave

7 before lunch so I think we're going to have a

8 discussion --

9 MR. SLATER: That's not true. How
10 did I violate the court order?

11 MR. BALL: I'll tell you but I
12 think we're going to have to do it -- it's going
13 to require something more than a sidebar. If
14 you've got one more question and you want to take
15 a break and then we do it --

16 MR. SLATER: That's fine.

17 MR. BALL: -- this is probably --

18 THE COURT: All right. Let's do
19 one more question.

20 See, here's the whole thing. I told you
21 I would let you play that tape later and --

22 MR. SLATER: This has nothing to
23 do with that, Judge. This is a different subject.

24 MR. BALL: That's right. It's a
25 different subject but it relates to the topic we

1 asked about.

2 MR. SLATER: I'm going to ask one
3 question right here (indicating).

4 MR. BALL: This relates to a
5 question we talked about right after lunch.

6 MR. SLATER: That's not true.
7 It's just not true.

8 I have one more question for Dr. Weber.
9 Then I can sit down. I assume they're done with
10 her --

11 THE COURT: Just promise me one
12 thing. That you won't ask one question that takes
13 a hundred more before you can sit down, okay?

14 MR. SLATER: That takes what?

15 THE COURT: A hundred more before
16 you can sit down.

17 MR. SLATER: Judge, I think I'm
18 doing pretty good.

19 THE COURT: I know a few times I
20 asked one question that I knew I shouldn't have
21 asked and then it takes me a hundred more to get
22 out of the rabbit hole, and that's all I'm asking
23 of you. You're a good lawyer but I'm just saying
24 let's don't.

25 MR. SLATER: I think I'm moving

1 pretty quick here.

2 THE COURT: All right. Mighty
3 fine. One more.

4 (The proceedings returned to open
5 court.)

6 Q. (By Mr. Slater) All right. I want you
7 to put up Exhibit P1920- -- you know what? Don't
8 put it up. I'm just going to ask you this and
9 we'll move through it.

10 Dr. Weber, you were shown the IFU by
11 counsel?

12 A. Yes.

13 Q. And I'm not going to put it up but you've
14 seen the picture of -- and we talked about it
15 earlier in your testimony -- the explanted mesh
16 from Joan Budke, correct?

17 A. Yes.

18 Q. Does the IFU or any of those documents
19 warn doctors that that was going to happen to
20 women?

21 MS. JONES: Objection. I --

22 Q. (By Mr. Slater) Yes or no. A simple
23 yes-or-no question.

24 THE COURT: What?

25 MS. JONES: Your Honor, I object

1 to this being beyond the scope of redirect. We
2 didn't talk about the picture that he's talking
3 about for Ms. Budke. It's beyond the scope.

4 THE COURT: Well, who put --
5 who --

6 MR. SLATER: I'm just asking if --

7 THE COURT: I'm sorry. It seems
8 like this is going on forever. How -- who first
9 put that video up?

10 MR. SLATER: You know what, Your
11 Honor? I'll withdraw it.

12 THE COURT: All right. Withdrawn.

13 MR. SLATER: It's no problem.

14 THE COURT: All right.

15 MR. SLATER: And that's my
16 redirect. Thank you very much.

17 THE COURT: Okay. Recross?

18 MS. JONES: Nothing further.

19 THE COURT: Nothing further.

20 Nothing further.

21 You may be excused.

22 MR. SLATER: And Your Honor,
23 obviously we're going to offer the exhibits we
24 used with Dr. Weber and the other ones but I
25 assume we can talk about that at one of the